UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE NEURONTIN MARKETING AND SALES PRACTICES LITIGATION	MDL Docket No. 1629 Master File No. 04-10981
THIS DOCUMENT RELATES TO: ALL ACTIONS	Judge Patti B. Saris

APPENDIX OF UNPUBLISHED AUTHORITIES FILED IN SUPPORT OF JOINT MEMORANDUM OF LAW OF THE CLASS AND COORDINATED PLAINTIFFS IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS

APPENDIX OF UNPUBLISHED AUTHORITIES

CASES **TAB**

TAB 1

IN THE UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF TEXAS

TYLER DIVISION

MATTHEW D. CARTWRIGHT, Individually and as Administrator of the Estate of BETHANY J. CARTWRIGHT, and as Next Friend of BLAKE NICHOLAS CARTWRIGHT and KRISTAN ALLYSSA CARTWRIGHT	§	
Plaintiffs,	§	
v.	§	6:04cv292
PFIZER, INC.	§	
Defendant.	§	

ORDER ON SUMMARY JUDGMENT

Came on this day for consideration the *Defendant Pfizer Inc's Motion for Summary Judgment (Federal Preemption) and Memorandum in Support* (Docket No. 13). After careful consideration, the Court is of the opinion that the following order should issue.

BACKGROUND AND PROCEDURAL HISTORY

This is a products liability case arising from the suicide death of Bethany Cartwright. According to the Plaintiffs' Complaint, two weeks prior to her death, Mrs. Cartwright was prescribed Zoloft by a local physician's assistant. She had taken Zoloft before, but was unable to remain on it consistently due to the side effects as well as the high cost of the drug. *Plaintiffs' Complaint*, ¶ 13. Zoloft is a member of the class of drugs referred to as "selective

serotonin reuptake inhibitors" ("SSRI"). SSRIs are used to treat major depressive disorder, from which Mrs. Cartwright suffered, as well as obsessive compulsive disorder, panic disorder, premenstrual dysphoric disorder, and social anxiety disorder.

After filling the prescription, her side effects became even more pronounced than before, including: "akathisia, insomnia, mania, agitation, emergent suicidality, emotional blunting and paradoxical worsening of depression." *Id.*, ¶ 14. On May 30, 2002, Mrs. Cartwright, apparently while folding laundry, put the laundry aside, brought the family's 22-caliber rifle into the bathroom, got into the bathtub, wrapped a towel around her head, placed the rifle in her mouth, and tragically, pulled the trigger.

The Plaintiffs, Mrs. Cartwright's estate and heirs, argue that Zoloft, a drug manufactured by the Defendant Pfizer, Inc., which Mrs. Cartwright began taking before her death, was a cause of her suicide. The Plaintiffs further contend that Pfizer had sufficient knowledge of the association between Zoloft and acts of self-harm to warn of this association prior to Bethany Cartwright's death and yet failed to warn of this association. The Defendant argues that the Plaintiffs' state law tort claims are preempted by federal law and must, therefore, be dismissed.

The Court believes that analysis of the instant motion requires a summary of the federal Food and Drug Administration's ("FDA") drug approval process. The federal Food, Drug, and Cosmetic Act ("FDCA") requires FDA approval of prescription medicines as "safe and effective" before they may be sold in this country. 21 U.S.C. §§ 355(d), 393(b)(2)(B).

To obtain approval, a manufacturer must submit a new drug application ("NDA") containing test results, results of clinical studies, and other information. *Id.*, § 355(b), (d). The FDCA requires the FDA to disapprove an NDA if the agency finds that

> (1) the investigations, reports of which are required to be submitted to the Secretary . . . , do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; (2) the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions; . . . (4) upon the basis of the information submitted to him as part of the application, or upon the basis of any other information before him with respect to such drug, he has insufficient information to determine whether such drug is safe for use under such conditions; or (5) evaluated on the basis of the information submitted to him as part of the application and any other information before him with respect to such drug, there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof; . . . or (7) based on a fair evaluation of all material facts, such labeling is false or misleading in any particular[.]

Id., § 355(d).

After approving an NDA, the FDA continues to monitor the drug's safety. The agency must withdraw its prior approval if at any time it finds that "clinical or other experience, tests, or other scientific data show that such drug is unsafe for use" or, "on the basis of new information," that the labeling "is false or misleading in any particular." *Id.*, § 355(e). An element the FDA considers crucial in determining whether a drug is safe is the labeling used to inform physicians about the drug's uses and risks. 50 Fed. Reg. 7452-01, 7470 (Feb. 22, 1985) ("Drug labeling serves as the standard under which

FDA determines whether a product is safe and effective."). The FDA regulates all such labeling, including "all written, printed, or graphic matter" used in marketing the drug. 21 C.F.R. § 1.3(a).

The FDA approves an NDA only if the agency "determines that the drug meets the statutory standards for safety ... and labeling." *Id.*, § 314.105(c). The FDA refuses approval if test results "show that the drug is unsafe for use under the conditions prescribed, recommended, or suggested in its proposed labeling or the results do not show that the drug product is safe for use under those conditions," or if "[t]here is insufficient information about the drug to determine whether the product is safe for use under the conditions prescribed, recommended, or suggested in its proposed labeling." *Id.*, § 314.125(a), (b)(3)-(4).

FDA regulations mandate the format and content of all the labeling sections – "Contraindications," "Warnings," "Precautions," and "Adverse Reactions" – and the risk information each section must contain. *Id.*, §§ 201.56, 201.57. The FDA states its product-specific labeling requirements in an "approvable" letter to the manufacturer. *Id.*, § 314.110(a) ("FDA will send the applicant an approvable letter if the application ... substantially meets the requirements of this part and the agency believes that it can approve the application ... if ... specific conditions (for example, certain changes in labeling) are agreed to by the applicant. The approvable letter will describe ... the conditions the applicant is asked to meet."). Approval of the NDA is "conditioned upon the applicant

incorporating the specified labeling changes exactly as directed, and upon the applicant submitting to FDA a copy of the final printed labeling prior to marketing." *Id.*, § 314.105(b).

On April 13, 1988, Pfizer submitted to the FDA an NDA seeking approval to market Zoloft to treat depression in adults. The NDA comprised 117 volumes of safety and efficacy data. The information in it and in supplemental submissions included detailed information about suicidality in patients given placebo, Zoloft, and active control drugs during clinical studies. *See Defendant's Motion for Summary Judgment*, Exhibit C.

On November 19, 1990, the FDA convened its Psychopharmacological Drugs Advisory Committee ("PDAC") to review the NDA and advise the FDA regarding the medicine's safety and efficacy. The PDAC consisted of psychiatrists, statisticians, and other experts chosen by the FDA from academic and research institutions throughout the nation. The PDAC voted unanimously that the evidence had shown that Zoloft "is safe when used in the treatment of depression." *Defendant's Motion for Summary Judgment*, Exhibit E.

The FDA issued its "approvable" letter on September 30, 1991. *See Defendant's Motion for Summary Judgment*, Exhibit F. Attaching proposed required labeling, the FDA stated, "We believe it presents a fair summary of the information available on the benefits and risks of [Zoloft]," and directed Pfizer to "use the proposed text verbatim." *Id.* at 1. The "Precautions" section of the labeling stated:

> Suicide – The possibility of a suicide attempt is inherent in depression and may persist until significant remission occurs. Close supervision of high

> risk patients should accompany initial drug therapy. Prescriptions for Zoloft (sertraline) should be written for the smallest quantity of capsules consistent with good patient management, in order to reduce the risk of overdose.

Id. at 5-6.

In addition, the "Adverse Reactions" section of the FDA's proposed required labeling listed "suicide attempt" as an "Infrequent" occurrence, explained that "infrequent adverse events are those occurring in 1/100 to 1/1000 patients," and stated, "It is important to emphasize that although the events reported occurred during treatment with Zoloft (sertraline), they were not necessarily caused by it." *Id.* at 14-15.

The FDA granted final approval on December 30, 1991. *See Defendant's Motion for Summary Judgment*, Exhibit G. It also prepared a final report summarizing the bases for its conclusion that Zoloft, with the required labeling, was safe and effective for treating depression. *See Defendant's Motion for Summary Judgment*, Exhibit H.

FDA's ongoing study of Zoloft and other SSRIs during the ensuing decade continued to find no causal relationship to suicide. Indeed, the FDA made six more explicit determinations that Zoloft was "safe and effective" with the FDA-required labeling. In 1996, the FDA approved Zoloft, as labeled, as safe and effective for treatment of adult obsessive compulsive disorder ("OCD"). *See Defendant's Motion for Summary Judgment*, Exhibit P. In 1997, FDA approved Zoloft, as labeled, as safe and effective for treatment of panic disorder and of pediatric OCD. *See Defendant's Motion for Summary Judgment*, Exhibits Q and R. In 1999, FDA approved Zoloft, as labeled, as safe

and effective for treatment of post-traumatic stress disorder ("PTSD"). *See Defendant's Motion for Summary Judgment*, Exhibit S. On May 16, 2002, only two weeks before Decedent's death, FDA approved Zoloft, as labeled, as safe and effective for treatment of premenstrual dysphoric disorder. *See Defendant's Motion for Summary Judgment*, Exhibit T. Most recently, on February 7, 2003, nine months after Decedent's death, FDA approved Zoloft, as labeled, as safe and effective for social anxiety disorder. *See Defendant's Motion for Summary Judgment*, Exhibit U.

The motion is now ripe for determination.

STANDARD OF REVIEW

A party is entitled to summary judgment on all or any part of a claim "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c). *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247, 106 S.Ct. 2505, 2510, 91 L.Ed.2d 202 (1986). The moving party must show initially that there is no genuine issue of any material fact. *Anderson*, 477 U.S. at 256, 106 S.Ct. at 2514. The movant may meet this burden by pointing out the absence of evidence supporting any essential element of the non-moving party's claim. *Celotex Corp. v. Catrett*, 477 U.S. 317, 23-25, 106 S.Ct. 2548, 553, 91 L.Ed.2d 265 (1986).

In deciding whether to grant a motion for summary judgment, the Court "review[s] the evidence and inferences to be drawn therefrom in the light most favorable to the nonmoving party." *Duplantis v. Shell Offshore, Inc.*, 948 F.2d 187, 189 (5th Cir. 1991) (citing

Duvall v. The Ritz Carlton Hotel Co., 946 F.2d 418, 420 (5th Cir. 1991), and quoting Fed. R. Civ. P. 56(c)). An issue is "genuine" only if the evidence could lead a reasonable jury to return a verdict for the nonmoving party. *Thomas v. Price*, 975 F.2d 231, 235 (5th Cir. 1992) (citing *Anderson v. Liberty Lobby, Inc.*, 477 U.S. at 255, 106 S.Ct. at 2513).

The opposing party may not rest on the mere allegations or denials of artful pleading, but must set forth affirmative facts that show a genuine issue for trial. *Anderson*, 477 U.S. at 256, 106 S.Ct. at 2514. This requires that the non-moving party make a showing sufficient to establish the existence of any element essential to that party's case, and on which that party will bear the burden at trial. *Nowlin v. R.T.C.*, 33 F.3d 498, 501 (5th Cir. 1994) (citing Celotex, 477 U.S. at 322-23, 106 S.Ct. at 2552-553).

ANALYSIS

Federal Preemption

This case presents a difficult and very close question of conflict preemption. The Supremacy Clause, article VI, clause 2, of the United States Constitution, preempts any state law that conflicts with the exercise of federal power. *Fid. Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 152-53 (1982). "Federal law will override state law under the Supremacy Clause when (1) Congress expressly preempts state law; (2) Congressional intent to preempt may be inferred from the existence of a pervasive federal regulatory scheme; or (3) state law conflicts with federal law or its purposes. *English v. General Elec. Co.*, 496 U.S. 72, 78-79 (1990).... '[T]he purpose of Congress is the ultimate touchstone in every preemption

case." *Frank v. Delta Airlines, Inc.*, 314 F.3d 195, 197 (5th Cir. 2002) (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996)).

The Defendant argues solely for the third option, conflict preemption. "[I]f a state common-law claim directly conflicted with a federal regulation ..., or if it were impossible to comply with any such regulation without incurring liability under state common law, [conflict] pre-emotion would occur." *Sprietsma v. Mercury Marine*, 537 U.S. 51, 65 (2002). Conflict preemption occurs either "where it is impossible for a private party to comply with both state and federal law" or where state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 372-73 (2000) (citation omitted). Federal regulations "have no less pre-emptive effect than federal statutes." *de la Cuesta*, 458 U.S. at 153. And the imposition of damages under state tort law is a form of state action subject to preemption. *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 881 (2000); *Chicago & N.W. Transp. Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311, 327 (1981).

Here, the Defendant argues that Plaintiff's attempt to use state tort law to require warnings that Zoloft causes suicide conflicts with (i) the FDCA and its implementing federal regulations, including FDA's specification of the suicide precautions required to be given with Zoloft, and (ii) FDA's determination that the suicide warnings advocated by Plaintiff are inappropriate and, if given, could be false, misleading, and harmful to patients. The Defendant further argues that the FDA has made clear that any such use of state tort law would impermissibly interfere with the agency's regulation of drug labeling

and impair the federal objective of ensuring that labeling of prescription medicines effectively communicates scientific information physicians need to make informed medical judgments. The Court disagrees.

State-law tort claims are preempted if they "stand as an obstacle to the accomplishment and execution of the full purposes and objectives" of federal law. *Geier*, 529 U.S. at 873. Even when state and federal laws have the same goal, a state tort claim is preempted if it would interfere with a method by which the federal law promotes that goal. *Int'l Paper Co. v. Ouellette*, 479 U.S. 481, 494 (1987) ("[I]t is not enough to say that the ultimate goal of both federal and state law is [the same]. A state law also is pre-empted if it interferes with the methods by which the federal statute was designed to reach this goal."); *Perez v. Campbell*, 402 U.S. 637, 650-52 (1971) (whether conflict exists between state and federal law depends not on state law's purpose, but on state law's effect on federal regulatory plan). The state law tort claims in the instant case do not fall into any of these categories. Thus, they are not preempted by federal law.

FDA-Approved Labeling

The Defendant asserts that the state-law requirement advocated by Plaintiff would conflict with the FDA's requirement that Pfizer use "verbatim" the labeling specified by the agency, and as such, Plaintiffs' claims are preempted. The Court is not persuaded. The FDCA and FDA's regulations do not conflict with Texas failure to warn law because they merely set minimum standards with which manufacturers must comply; they *expressly* do not prohibit a manufacturer from "add[ing to] or strengthen[ing] a

contraindication, warning, precaution, or adverse reaction. 21 C.F.R. § 314.70(c)(6)(iii)(A). This is consistent with Congress' primary goal in enacting the FDCA, which is "to protect consumers from dangerous products." *United States v. Sullivan*, 332 U.S. 689, 696, 68 S. Ct. 331, 335, 92 L. Ed. 297 (1948). The minimum standards approach is also consistent with Congress' stated intent that the FDCA "'must not weaken the existing laws', but on the contrary 'it must strengthen and extend that law's protection of the consumer.'" *United States v. Dotterweich*, 320 U.S. 277, 282, 64 S. Ct. 134, 137, 88 L. Ed. 48 (1943). With little exception, courts that have considered this exact issue have concluded that state failure to warn claims are not preempted by the FDCA and its attendant regulations.

Numerous courts over the years have recognized that the FDCA and its associated regulations set out minimum requirements that drug manufacturers must follow which may be supplemented by state tort laws which are stronger. "FDA regulations are generally minimal standards of conduct ...." *Hill v. Searle Laboratories, Inc.*, 884 F.2d 1064, 1068 (8th Cir. 1989). "An FDA determination that a warning is not necessary may be sufficient for federal regulatory purposes but still not be sufficient for state tort law purposes." *Wells v. Ortho Pharmaceutical Corp.*, 788 F.2d 741, 746 (11th Cir. 1986).

At one time, the FDA did not view its standards regarding drug warnings as the minimum requirement. Prior to 1965, "the FDA regulations applicable to drugs prohibited companies from adding warnings or other information without prior approval." *Caraker v. Sandoz Pharmaceuticals Corp.*, 172 F. Supp. 2d 1018, 1034 (S.D. Ill. 2001)

(citing 25 Fed. Reg. 12,592, 12,595 (1960)). In 1965, however, the FDA changed its regulations to allow "labeling changes related to safety to be 'placed into effect at the earliest possible time,' the goal of which was 'to enable prompt adoption of such changes.'" *Id.* (citing 30 Fed. Reg. 993 (1965)).

Since 1965, the FDA's regulations permit a manufacturer "[t]o add or strengthen a contraindication, warning, precaution, or adverse reaction," without prior approval by the FDA. 21 C.F.R. § 314.70(c)(6)(iii)(A); *In re Tetracycline Case*, 747 F. Supp. 543, 549-50 (W.D. Mo. 1989). In addition, a drug manufacturer may "add or strengthen a statement about drug abuse, dependence, psychological effect, or overdosage," without prior approval (21 C.F.R. § 314.70(c)(6)(iii)(B)), and "add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product," without prior approval. 21 C.F.R. § 314.70(c)(6)(iii)(C). Thus, FDA's position regarding stronger warnings by drug manufacturers, as expressed through *its own regulations*, is that a manufacturer could, and should, provide stronger warnings as soon as such a warning is warranted.

Further, the regulations require a manufacturer to issue a warning whenever there is "reasonable evidence of an association of a serious hazard with a drug; *a causal relationship need not have been proved.*" 21 C.F.R. § 201.57(e) (emphasis added). In fact, this same regulation requires that "black box" warnings be used for drugs which have problems "that may lead to death or serious injury," the very same black box

warnings that the FDA's pharmoneurological drug advisory committee ("PDAC") recommended be placed on all SSRI drugs, including Zoloft, regarding *suicidality in children and adolescents*. *See Plaintiffs' Opposition to Defendant's Motion for Summary Judgment*, Exhibit 80. Thus, it is clear to this Court that manufacturers must act quickly to warn regarding possibly deadly side effect associated with a drug because the FDA only sets forth minimum standards for labeling and safety of drugs.

It is important to note that there is a strong presumption against implied conflict preemption in matters dealing with the FDA given the FDA's ability to promulgate regulations which can have preemptive effect. *Hillsborough County, Fla. v. Automated Medical Laboratories, Inc.*, 471 U.S. 707, 721 (1985). Recently, the Supreme Court clarified the application of the conflict preemption doctrine in the *Geier v. Am. Honda Motor Co.* case. In that case, the Court held that a federal statute which gave automobile manufacturers the choice between two different passive restrain systems (airbags and automatic shoulder belts) preempted any state tort law requirement that an automobile be manufactured with airbags. *Id.*, 529 U.S. at 886. The Court held that state tort law requirements would pose an "obstacle" to the accomplishment of a complex federal regulatory scheme because the regulation in question set forth a specific balance regarding the deployment of airbags and, thus, any additional state law requirements would upset this balance. *Id.* at 885-86. However, the court limited its conflict preemption holding to the language of the federal regulation at question and stated that "the language of [the regulation] and the contemporaneous [agency] explanation is clear

enough - even without giving [the agency's] own view special weight." *Id.* at 886. Importantly, the Court found that the federal regulation did not impose a minimum standard, but rather, provided the manufacturer with a "range of choices." *Id.* at 874-75.

Consistently, courts have held that state law failure to warn cases are not preempted by the FDCA or its associated regulations. In *Osburn v. Anchor Laboratories, Inc.*, 825 F.2d 908, 912-913 (5th Cir. 1987), the Fifth Circuit held that preemption was not appropriate in a failure to warn case under Texas law because the FDA regulations "specifically permitted [the manufacturer] to add additional warnings to a previously approved label as soon as it became aware of the necessity to do so – without any need to first obtain FDA approval of the supplemental warning."[1] The Court concluded that the "FDA regulations [] did not prevent [the manufacturer] from adding to its label warnings ... ," and, thus, "federal law neither made it practically (nor legally) impossible, nor would it have posed an obstacle to accomplishing the objectives of the FDCA." *Id.*

In *Hurley v. Lederle Laboratories*, 863 F.2d 1173 (5th Cir. 1988), the Fifth Circuit, again, found that the FDCA and its regulations did not preempt a state law failure to warn claim against a vaccine manufacturer. The Court canvassed previous preemption decisions and stated that "the great majority of United States district courts which have addressed this issue have ruled against preemption." *Id.* at 1176. Indeed, the Court cited *seventeen* previous decisions which ruled against preemption. The Court stated that in a situation where there is no express preemption clause, "[c]ourts should be reluctant to

[1] In *Osburn*, the Court was interpreting FDA regulations applicable to veterinary drugs. However, the FDA regulations regarding prescription drugs for humans are virtually identical in this regard. *See* 21 C.F.R. § 314.70(c)(6)(iii)(A).

find that federal law *implicitly* preempts state law." *Id.* (emphasis in original). With regard to the FDCA, the Court stated that "FDA regulation does not generally preempt stricter state law standards for medical products." *Id.* at 1177; *see also Tobin v. Astra Pharmaceutical Prods., Inc.*, 993 F.2d 528 (6th Cir. 1993) (no preemption for state law design defect claim against prescription drug manufacturer).

Recently, a number of courts who have considered this exact issue have ruled in favor of no preemption. In *Motus v. Pfizer, Inc.*, 127 F. Supp. 2d 1085 (C.D. Cal. 2000), a district court in California ruled against Pfizer's Motion for Summary Judgment regarding preemption stating that, "[a]lthough certain suicide warnings could violate federal law because they were false or misleading or were not based on the 'essential scientific information needed' for safe use, the Court does not think that any and every suicide-related warning that might be required under state law is necessarily false or misleading ...." *Id.* at 1095. On appeal, the United States filed an *amicus* brief in favor of the Defendant's position. In the *amicus* brief, the United States urged that any warning of a causal relation between Zoloft and suicide would have "misbranded" the drug. *See Defendant's Motion for Summary Judgment*, Exhibit B, p. 17. The United States further stated that when the plaintiff in *Motus* was prescribed Zoloft, "any warning, no matter how worded, that could reasonably have been read as describing or alluding to such a relation would have been false or misleading, and therefore in conflict with federal law because there was no (and still is not) scientific support for such a warning." *Id.* at 21. Here, on numerous occasions, the Defendant refers to the *amicus* brief for support of its

arguments. The main flaw in Defendant's argument now is that the Plaintiffs have produced evidence to the contrary. There *is* support for such a warning.

Likewise, in *Caraker v. Sandoz Pharmaceuticals Corp.*, 172 F. Supp. 2d 1018 (S.D. Ill. 2001), the district court ruled against preemption because the manufacturer was explicitly authorized by the FDA's regulations to add or strengthen its warnings without prior FDA approval. *Id.* at 1033-34. The *Caraker* court cited to the FDA commissioner's statement that "labeling regulations do not prohibit a manufacturer, packer, relabeler, or distributer from warning health care professionals whenever possibly harmful adverse effects associated with the use of the drug are discovered." *Id.* at 1034 (citing 44 Fed. Reg. 37,434, 37,447 (1979)).

Thus, numerous federal courts who have considered this issue have determined that preemption is not appropriate. On the other hand, Pfizer cites to a number of cases which hold that preemption is appropriate in this case. However, Pfizer's citations are misleading because these cases are express preemption cases. Express preemption caselaw has no application to this case because there is no provision in the FDCA or its regulations regarding prescription drugs which purport to preempt state law.

In *Brooks v. Howmedica, Inc.*, 273 F.3d 785 (8th Cir. 2001), the Court held that the plaintiff's state law failure to warn claims against a medical device manufacturer were preempted because of an express preemption clause in the Medical Device Amendments ("MDA") to the FDCA, codified at 21 U.S.C. § 360k. Importantly, the Court stated that preemption was appropriate under the preemption clause because the manufacturer had gone through the rigorous approval requirements required for new medical devices.

Brooks, *supra*, 273 F.3d at 794-95. Although the approval process for Zoloft may have been equally rigerous, Congress and the FDA has chosen not to include an express preemption clause in the statutes and regulations for prescription drugs. Clearly, Congress knows how to enact FDA legislation that contains a preemption clause. Thus, the absence of any such clause with respect to prescription drugs demonstrates an implied intent not to preempt cases, such as this.

Similarly, in *Martin v. Medtronic, Inc.*, 254 F.3d 573 (5th Cir. 2001) and *Kemp v. Medtronic, Inc.*, 231 F.3d 216 (6th Cir. 2000), the courts considered the same preemption issue pursuant to the express preemption clause in the MDA. Both courts held that the plaintiffs' failure to warn claims were preempted because both of the medical products in question had been subjected to the rigorous approval process for new medical devices. 254 F.3d at 584-85; 231 F.3d at 236-37. However, these cases, just like *Brooks*, are inapplicable to the situation presented here because there is no express preemption clause regarding prescription drugs. Thus, Pfizer's reliance on these cases is misplaced.

Finally, Pfizer cites to the newly published case of *Horn v. Thoratec Corp.*, 376 F.3d 163 (3d Cir. 2004), for the proposition that conflict preemption should apply in this case. In *Horn*, the Court stated that the state tort law claims were in "severe tension" with the federal requirement regarding medical devices. *Id.* at 177. However, *Horn*, just like the courts in *Brooks*, *Martin*, and *Kemp*, was interpreting the *express* preemption clause of the MDA. Importantly, this clause reads "[n]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement - (1) which is different from, *or in addition to*, any requirement applicable

to this chapter to the device." 21 U.S.C. § 360k(a) (emphasis added); *Horn, supra*, 376 F.3d at 166. Thus, by this provision, Congress has clearly expressed an intent that stricter state law requirements should not be allowed. The exact *opposite* is true with prescription drugs as has been discussed previously.

Thus, the cases cited by Pfizer are, by and large, completely inapplicable to the question before this Court. The sole question this Court must decide is whether plaintiffs' state law failure to warn claims conflict with the federal requirements regarding prescription drugs such that the state claims should be preempted. As stated above, the federal labeling requirements for prescription drugs are minimum standards; states can impose stricter requirements regarding labeling and warnings if they so choose. The only limiting regulation is that the warnings must not be false or misleading. Given the hearings by both Congress and the FDA regarding suicidality, the FDA's PDAC's recent decision to recommend black box warnings regarding suicidality in children and adolescents, and the numerous experts who have concluded that there is a link between SSRIs, like Zoloft, and suicidality, it would be inconceivable to this Court to argue that an additional warning regarding suicidality would be false or misleading.

FDAs Objective

Pfizer argues that preemption is appropriate in this case because the Plaintiffs' state law failure to warn claims will "interfere" with the FDA's objective "of ensuring that all warnings are supported by scientific evidence sufficient to demonstrate that the warnings are accurate and not misleading." *Defendant's Motion for Summary Judgment*, pp. 24-25. Additionally, inclusion of scientifically unsupported warnings also would

interfere with the FDA's goal of providing patients with the benefit of appropriate medications. According to Pfizer, "scientifically unsupported warnings" in drug labeling "deafen doctors to the labeling's important, scientifically based information." *Id.*, p. 25. However, Pfizer ignores the FDA's *primary* objective, which is to protect consumers. *United States v. Dotterweich*, 320 U.S. 277, 282, 64 S. Ct. 134, 137, 88 L. Ed. 48 (1943).

Clearly, the FDA, through its regulations, recognizes its important dual purpose – to provide scientifically accurate information and to protect consumers – because it allows, and even encourages, manufacturers to be proactive when learning of new safety information related to their drug. As previously stated, the FDA's regulations allow a manufacturer to add to or strengthen warnings *without prior FDA approval*. 21 C.F.R. § 314.70(c)(6)(iii)(A). In fact, the manufacturer must do this "as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved."[2] 21 C.F.R. 201.57(e). Thus, the FDA has made clear, through its regulations, that manufacturers, not the FDA, are tasked with the responsibility of taking proactive steps once a manufacturer learns of "reasonable evidence of an association of a serious hazard with a drug." *Id.*

Likewise, Texas products liability law requires manufacturers to provide consumers (or doctors in the case of products, such as drugs, where the learned intermediary doctrine applies) with warnings regarding "reasonably foreseeable or

[2] It is important to note that although Pfizer has characterized the Plaintiffs' failure to warn claim as requiring Pfizer to issue a "drug-causes-suicide-warning" (*Defendant's Motion for Summary Judgment*, p. 26), in fact, the Plaintiffs are simply seeking a warning regarding the association between suicidality and Zoloft - an association that Pfizer has known about for many years.

scientifically discoverable" dangers at that time the product is sold. *See Wood v. Phillips Petroleum Co.*, 119 S.W.3d 870, 873 (Tex. 2003) (citing *Borel v. Fibreboard Paper Prods. Corp.*, 493 F.2d 1076, 1088 (5th Cir. 1973)). This duty to warn requires manufacturers to "test and inspect its product" to determine whether warnings are necessary or appropriate. *Id.* at 873-74. This state law duty regarding warnings is directly parallel with the FDA's requirements that manufacturers provide safety warnings to consumers as soon as there is "reasonable evidence." It is clear that Texas state law does not require manufacturers to issue warnings that are "scientifically unsupported." Instead, Texas, just like the FDA, requires warnings when there is safety information that is scientifically discoverable. *Wood*, 119 S.W.3d at 873. Thus, Texas law compliments and is parallel to the FDA's regulations regarding safety warnings and, thus, does not interfere with the objectives of the FDA.

Ultimately, it is clear that Pfizer's arguments regarding the supposed thwarting of the FDA's objectives in this case are misguided. The evidence unequivocally proves that the FDA's objective, as expressed through its regulations, demonstrate that manufacturers should provide consumers with all the safety information about their drugs as soon as the information is known, which is exactly what Texas law requires. Thus, there is no FDA objective that is being subverted or thwarted.

CONCLUSION

After a thorough review of the pleadings, the briefs, and the exhibits submitted as summary judgment evidence, the Court holds that summary judgment should be denied and this case should proceed. This case presents a difficult and very close question of

conflict preemption. However, when viewing all of the evidence in the light most favorable to the Plaintiff, the Court finds that the Plaintiff has provided evidence to establish a genuine issue as to a material fact regarding the Defendant's federal preemption defense. As such, the Plaintiffs' state law tort claims are not preempted by federal law and must, therefore, not be dismissed.

It is therefore

ORDERED that the *Defendant Pfizer Inc's Motion for Summary Judgment (Federal Preemption) and Memorandum in Support* (Docket No. 13) is hereby **DENIED**.

SIGNED this 31st day of March, 2005.

William M. Steger

WILLIAM M. STEGER
UNITED STATES DISTRICT JUDGE

TAB 2

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

TRANSMITTED BY FACSIMILE

Henry A. McKinnell, Jr., Ph.D.
Chairman of the Board
and Chief Executive Officer
Pfizer Inc.
235 East 42nd Street
New York, NY 10017

Re: NDA 19-835, 20-346, 21-621
Zyrtec® (cetirizine HCl) Tablets, Syrup, and Chewable Tablets
MACMIS # 12799

WARNING LETTER

Dear Dr. McKinnell:

The Division of Drug Marketing, Advertising, and Communications (DDMAC) has reviewed three direct-to-consumer (DTC) print advertisements (ads) titled "Tired of your allergy medicine not working?" (airplane) (ID #ZY179738), "Tired of your allergy medicine not working?" (office) (ID #ZY182060A) and "Maybe it's time to switch allergy medicines" (ID #ZY182060) for Zyrtec® (cetirizine HCl) Tablets, Syrup, and Chewable Tablets submitted by Pfizer Inc. (Pfizer) under cover of Form FDA 2253. The print ads make superiority claims about Zyrtec by suggesting it is clinically superior to some other allergy medicines. To our knowledge, these claims have not been demonstrated by substantial evidence or substantial clinical experience. Therefore, these claims misbrand your drug product in violation of the Federal Food, Drug, and Cosmetic Act (Act) and FDA implementing regulations. See 21 U.S.C. § 352(n); 21 CFR 202.1(e)(6).

Background

Approved Product Labeling

According to the approved product labeling (PI), Zyrtec is FDA-approved for the following indications:

> **Seasonal Allergic Rhinitis [SAR]**: ZYRTEC is indicated for the relief of symptoms associated with seasonal allergic rhinitis due to allergens such as ragweed, grass and tree pollens in adults and children 2 years of age and older. Symptoms treated effectively include sneezing, rhinorrhea, nasal pruritus, ocular pruritus, tearing, and redness of the eyes. **Perennial Allergic Rhinitis [PAR]**: ZYRTEC is indicated for the relief of symptoms associated with perennial allergic rhinitis due to allergens such as dust mites, animal dander and mold in adults and children 6 months of age and older. Symptoms treated effectively include sneezing, rhinorrhea, postnasal discharge, nasal pruritus, ocular pruritus, and tearing.

According to the PI, the most common adverse reactions associated with the use of Zyrtec in persons 12 years and older include somnolence, fatigue, and dry mouth.

The Zyrtec PI also includes a specific precaution regarding somnolence, which states that "due caution should...be exercised when driving a car or operating potentially dangerous machinery. Concurrent use of ZYRTEC with alcohol or other CNS depressants should be avoided because additional reductions in alertness and additional impairment of CNS performance may occur."

Regulatory History

DDMAC has sent you three previous untitled letters for Zyrtec Tablets/Syrup since 1998. On March 4, 1998, DDMAC issued an untitled letter on a sales brochure that made implied clinical superiority claims based on comparative pharmacodynamic data, but which were not supported by substantial evidence or substantial clinical experience. On December 21, 1998, DDMAC issued an untitled letter on the dissemination of a bibliography of "Abstracts of Selected Zyrtec Literature," which listed abstracts that promoted the superiority of Zyrtec over other antihistamines in the absence of substantial evidence or substantial clinical experience to support that claim, as well as a detailer that implied an unsubstantiated risk of serious cardiovascular events with Claritin. On April 30, 2002, DDMAC issued an untitled letter on a DTC broadcast ad for failing to disclose risk information and for failing to make adequate provision for dissemination of the PI.

On July 8, 2003, DDMAC and the Federal Trade Commission (FTC) sent a joint letter to Pfizer expressing our concerns about promotional materials that compared Zyrtec to other allergy medicines, and which specifically communicated the concern that "consumers might misinterpret these claims as suggesting that Zyrtec has been demonstrated to work better at treating PAR symptoms than other allergy medicines or that the other medicines have been demonstrated to be ineffective for treating PAR symptoms." The letter further stated:

> "We are unaware of any evidence that Zyrtec is clinically superior to various OTC and prescription oral allergy medicines. Nor are we aware of evidence that other antihistamines are not effective in PAR. It is therefore important that your advertising distinguish between having evidence of effectiveness in, and approval for, PAR, as Zyrtec does, and any suggestion that Zyrtec is actually more effective."

Unsubstantiated Superiority Claims

The three DTC print ads cited above make false or misleading claims that Zyrtec is clinically superior to some other allergy medicines, namely, that Zyrtec "works" and that at least some other allergy medicines do not work.

The "Tired of your allergy medicine not working?" (airplane) ad features a picture of two people seated on an airplane. A man is sneezing and the text next to his picture states: "In the right seat. On the wrong allergy medicine." The woman in the seat next to him, who is not sneezing, is looking at him. The text next to her picture states: "On top of things. On Zyrtec." The prominent callout

headline below the picture states "Tired of your allergy medicine not working? Good thing there's Zyrtec."

The "Tired of your allergy medicine not working?" (office) ad features a picture of people in an office setting. A woman appears to be sneezing into a tissue, and the text next to her picture states: "On the wrong page. On the wrong allergy medicine." The woman next to her is on the phone and is looking over at her, with the text next to her picture stating: "On the ball. On Zyrtec." The prominent callout headline below the picture states "Tired of your allergy medicine not working? Good thing there's Zyrtec."

The "Maybe it's time to switch allergy medicines" ad features the same office setting as the prior ad. The text next to the woman wiping her nose states: "Needs to switch allergy medicines." The text next to the woman on the phone states: "Needs to switch desks." The prominent callout headline below the picture states: "Maybe it's time to switch allergy medicines when your co-worker volunteers to swap seats with the intern."

For each of the ads, the text under the headline states: "Your allergy medicine should work on all of your indoor and outdoor allergies. Really work. Why put up with a medicine that only treats outdoor allergies? Shouldn't it cover both?" Each ad also tells the consumer to ask their doctor "about switching to prescription Zyrtec," "So you – and your seatmates – can feel good the whole flight" or "So you – and your co-workers – can feel good in the office," respectively.

The overwhelming message from the text and the visuals of these ads is the comparative claim that Zyrtec is more effective in treating allergies in general, or certain types of allergies, than some other allergy products, which are not effective. As noted above, FDA is not aware of substantial evidence or substantial clinical experience demonstrating that Zyrtec is clinically superior to any other available OTC and prescription oral allergy medicine. In addition, it is misleading to suggest that patients taking Zyrtec would be "On top of things" or "On the ball" as compared to patients on other allergy drugs. Furthermore, FDA is not aware of substantial evidence or substantial clinical experience demonstrating that other antihistamines are not effective in treating PAR (i.e., have been tested and failed), as is suggested by these ads. Finally, FDA is not aware of substantial evidence or substantial clinical experience showing that patients who fail on other allergy drugs will be effectively treated by Zyrtec, as the ad suggests. Therefore, these claims are false or misleading.

FDA does not object to the dissemination of truthful, non-misleading statements about approved indications, and we acknowledge that Zyrtec is approved for a broader range of indications than many other antihistamines. Therefore, we do not object to the statement in the ads that, "No other antihistamine is approved to treat more allergies than Zyrtec." Rather, our concern is that this factual statement, which follows the other claims and visuals noted above, does not correct the overall misleading impression that superior effectiveness, not merely a comparison of indications, is being promoted in these ads. Absent substantial supporting evidence or clinical experience, the ads suggest that the absence of a particular claim in another antihistamine's labeling affirmatively means that the antihistamine does not work for that claim. Likewise, they also suggest that Zyrtec is more effective -- either in general or in specific cases -- than at least some other antihistamines.

Conclusion and Requested Action

The DTC print ads "Tired of your allergy medicine not working?" and "Maybe it's time to switch allergy medicines" make false or misleading claims that Zyrtec is clinically superior to other allergy medicines (21 U.S.C. § 352(n); 21 CFR 202.1(e)(6)).

DDMAC requests that Pfizer immediately cease the dissemination of violative promotional materials for Zyrtec that contain claims the same as or similar to those described above. Please submit a written response to this letter on or before April 27, 2005, stating whether you intend to comply with this request, listing all violative promotional materials for Zyrtec that contain claims the same as or similar to those described above, and explaining your plan for discontinuing use of such materials. Because the violation described above is serious and repeated, we request, further, that your submission include a comprehensive plan of action to disseminate truthful, non-misleading, and complete corrective messages about the issues discussed in this letter to the audience(s) that received the violative promotional materials. Please direct your response to me at the Food and Drug Administration, 5600 Fishers Lane, HFD-42, Room 8B-45, Rockville, MD, 20857, facsimile at (301) 594-6759. In all future correspondence regarding this matter, please refer to MACMIS #12799 in addition to the NDA number. We remind you that only written communications are considered official.

The violations discussed in this letter do not necessarily constitute an exhaustive list. It is your responsibility to ensure that your promotional materials for Zyrtec comply with each applicable requirement of the Act and FDA implementing regulations.

Failure to correct the violation discussed above may result in FDA regulatory action, including seizure or injunction, without further notice.

Sincerely,

{See appended electronic signature page}

Thomas W. Abrams, RPh, MBA
Director
Division of Drug Marketing,
Advertising, and Communications

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/
Thomas Abrams
4/13/05 03:48:26 PM

TAB 3

NOT FOR PUBLICATION WITHOUT THE APPROVAL OF THE COMMITTEE ON OPINIONS

CAROL E. HIGBEE, J.S.C.

1201 Bacharach Boulevard
Atlantic City, NJ 08401-4527
(609) 343-2190

MEMORANDUM OF DECISION ON MOTION
Pursuant to Rule 1:6-2(f)

CASE:	**International Union of Operating Engineers Local No. 68 Welfare Fund, Individually and on behalf of all others similarly situated v. Merck & Co., Inc.**
DOCKET #:	**ATL-L-3015-04**
DATE:	**July 8, 2004**
MOTION:	**Defendant's Motion for Summary Judgment**
ATTORNEYS:	**Wilfred P. Coronato, Esq. – Attorney for Defendant** **Christopher A. Seeger, Esq. – Attorney for Plaintiff**

Having carefully reviewed the papers submitted and oral arguments presented, I have ruled on the above Motion as follows:

The plaintiff, International Union of Operating Engineers Local No. 68 Welfare Fund (the Fund or the plaintiff) is a joint union-employer trust fund which pays for prescription drugs purchased by its members for their consumption. Such "third party payor" funds are common today as most prescription drugs are purchased through prescription plans.

The Fund filed a two-count class action complaint against the defendant Merck & Co., Inc. (Merck) who is the manufacturer of the prescription drug VIOXX®. Merck is a New Jersey corporation. The Fund is organized and operating in New Jersey. The complaint was filed in New Jersey on behalf of "all third party payors in the United States" who have paid for the prescription drug VIOXX®. The issue of class certification is not presently before the Court.

The Fund alleges that Merck's marketing and advertising of the drug VIOXX® was fraudulent and misrepresented the safety and efficacy of the drug.

The Fund alleges specifically that VIOXX® is a cox-2 specific inhibitor used in the treatment of inflammation and pain and is among the class of drugs known as NSAIDs. Merck introduced VIOXX® and sold it initially at a cost of $72.00 for a monthly supply. In contrast NSAIDs on the market already sold for $9.00 or less for the same supply. Traditional NASIDs inhibit both cox-1 and cox-2 enzymes. Cox–1 enzyme is believed to have a protective effect on the gastrointestinal system and the traditional NASIDs were known to pose a risk of ulcer and other gastrointestinal problems. The Fund alleges that Merck misrepresented that VIOXX® had a significantly reduced risk of these side effects. The Fund alleges VIOXX® was promoted and marketed by Merck as much safer and more effective than the much cheaper NASIDs already on the market. The Fund states that in reliance on these claims by Merck, they approved, as did other third party payors, inclusion of VIOXX® as a preferred prescription drug and agreed to pay for use of VIOXX® by their members.

The Fund specifically alleges that Merck initially misrepresented the safety of the drug to get it on drug formularies so they could get a large share of the market for these types of drugs. In the year 2000, the Fund states that sales of VIOXX® exceeded two billion dollars and VIOXX® acquired 23% of the NASIDs market despite the significantly higher cost.

The plaintiff alleges that the representation by Merck that VIOXX® was safer than traditional NASIDs was false. The plaintiff alleges that VIOXX® also poses a risk of ulcers and gastrointestinal side effects and that its marketing and promotion as a safer alternative was false. In addition, the Fund alleges that VIOXX® produced a high rate of cardiovascular events,

including heart attacks. They allege that the defendant intentionally failed to disclose the level of risk of cardiovascular events caused by the drug.

In the complaint, plaintiffs refer to specific FDA warning letters sent to the defendant. The complaint references a letter sent by the FDA on July 16, 1999 warning defendant that its advertisements failed to provide adequate risk information. It also references a December 1999 FDA letter to defendant that warns them that some of its promotional pieces were "false & misleading." An additional letter issued to defendant on September 17, 2001 includes statements that Merck had minimized "potentially serious cardiovascular findings" from a VIOXX® study.

The complaint asks for economic damages because the Fund was mislead into paying higher prices for VIOXX® than for traditional NASIDs. The Fund claims it relied on the false statements and the suppression of information from Merck in order to approve VIOXX® as a preferred drug for its members because it had more benefits and less risks to its members than much cheaper NASIDs on the market. The complaint states two causes of action, one for common law fraud and misrepresentation and one for fraud under the New Jersey Consumer Fraud Act (N.J.S.A. 56:8-1, et seq.).

Merck moves to strike both counts of the complaint. Merck states the first count is deficient because the complaint is not specific enough for a fraud count. In order to make a valid claim for fraud, plaintiff must allege a material misrepresentation and reasonable reliance thereon. See Gennari v. Weichert Co. Realtors, 148 N.J. 582, 610 (1997). The allegations of misrepresentation must be pled with particularity under Rule 4:5-8(a) which states in "all allegations of misrepresentation, fraud . . . particulars of the wrong, with dates and items if necessary, shall be stated insofar as practicable."

This is a motion to dismiss a complaint. Discovery is still in process. Over a million pages of documents, including advertising and marketing materials and drug studies have been provided by defendant to plaintiff. Depositions have started but most are still ahead.

Defendants cite to several federal cases that were dismissed for failure to plead with particularity under Fed. R. Civ. P. 9(b). In this case, the complaint does not simply make a general allegation of fraud. The complaint describes the misrepresentations that VIOXX® was more safe and more effective than other NASIDs on the market as being the heart of the misrepresentation. The complaint states with even more particularity that representations that VIOXX® caused less gastrointestinal side effects than other NASIDs on the market and the omission or minimizing of known dangers of cardiovascular side effects are the basis of the claim of misrepresentation. These are specific misrepresentations. It is not "practicable" in a case such as this to allege each and every specific statement made and the date and place in the complaint.

There has to be a balance between the need for specificity so the defendant understands exactly what is being alleged as fraud and the practical ability of the plaintiff to specify each individual misstatement before discovery is completed in a case that involves billions of dollars of sales.

The Federal Rules and the New Jersey Rules on pleading of fraud are similar but the State Rule addresses practicality. The purpose is the same. In the case of Seville Industrial Machinery Corp. v. Southmost Machinery Corp., 742 F.2d 786 (1984) the U. S. Third Circuit Court reversed a decision of the U.S. District Court of New Jersey where plaintiff's complaint had been dismissed for failing to plead the underlying acts of fraud with sufficient particularity.

The U.S. Third Circuit Court states that the U.S. District Court confused what must be "pleaded with what must be proved". The decision states:

> Rule 9(b) requires plaintiffs to plead with particularity the "circumstances" of the alleged fraud in order to place the defendants on notice of the precise misconduct with which they are charged, and to safeguard defendants against spurious charges of immoral and fraudulent behavior. It is certainly true that allegations of "date, place or time" fulfill these functions, but nothing in the rule requires them. Plaintiffs are free to use alternative means of injecting precision and some measure of substantiation into their allegations of fraud.

The VIOXX® complaint identifies with specificity the nature of the misrepresentations. The specific FDA warning letters referenced in the complaint add both more precision and some measure of substantiation to the allegations.

The allegations are just that. They remain unproven but are sufficiently specific to allow the defendant to understand what they must defend against. In Florian Greenhouse v. Cardinal IG Corp., 11 F.Supp.2d 521 (U.S. Dist.Ct. N.J. 1998) the Court stated "the most basic consideration in judging the sufficiency of a pleading is whether it provides adequate notice to an adverse party to enable it to prepare a responsive pleading."

In In re The Prudential Insurance Company of American Sales Practices Litigation 975 F.Supp. 584, in an opinion dealing with complex insurance fraud allegations, the U.S. District Court of N.J. held:

> Nor, under these circumstances, is plaintiffs' failure to attach specific documents to which the complaint refers, or to quote from them verbatim, fatal to their claims. Cf. In re VMS Secs. Lit., 752 F.Supp. 1373, 1386 (N.D.Ill.1990). In complex corporate fraud case such as this one, "a description of the nature and subject matter" of the alleged misrepresentations or omissions may be sufficient "even absent allegations with respect to the exact factual context or words constituting the misrepresentation." In re Midlantic Corp. Shareholder Lit., 758 F.Supp. 226, 231 (D.N.J.1990), citing Commodity Futures Trading Com'n v. American Metal Exchange Corp., 693 F. Supp. 168, 190-91 (D.N.J.1988).

The Court finds that the complaint alleges fraud with sufficient particularity to fulfill the purpose of the Rules.

This Court notes that in Shapo v. O'Shaughnessy, 246 F.Supp.2d 935 (U.S. Dist. Ct. Ill. 2002) it was recognized that although the Third Circuit and Eighth Circuit have looked to the purpose of Rule 9(b) and don't require that every complaint contain "who, what, when, where and how" in complete detail, the Seventh Circuit does usually still require all such details. The decision points out, however, that even the Seventh Circuit recognizes that these requirements are loosened upon a showing a plaintiff needs discovery to obtain particulars of fraudulent scheme where the scheme itself is alleged with particularity. This reasoning would also support the Court's decision to decline to dismiss plaintiff's complaint for failure to properly plead their fraud claim. Discovery is necessary to flesh out the misrepresentations cited in the FDA warning letters.

The defendant Merck also argues that plaintiff's allegations of fraudulent omissions are defective because there was no fiduciary relationship between plaintiff and the defendant and therefore no duty to disclose information to plaintiffs. Pharmaceutical companies have a duty to disclose information to the public including to those who directly purchase their drugs. See Perez v. Wyeth Labs, 161 N.J. 1 (1999), at 20-21, in which the Court stated:

> It is one thing not to inform a patient about the potential side effects of a product; it is another thing to misinform the patient by deliberately withholding potential side effects while marketing the product as a efficacious solution to a serious health problem.

This Court sees no reason why the duty to be honest about the safety and usefulness of a drug when marketing it as a product for sale should not extend to the third party payors who actually pay for the purchase of drugs for members.

The complaint alleges that the plaintiff relied upon the misrepresentations of defendant Merck when approving VIOXX® for purchase by its members. It alleges plaintiff paid an excessive price to buy VIOXX® at a substantial premium over other drugs on the market because of these misrepresentations. The defendants argue that there really was no reliance. The claim is pled appropriately. The issue of whether there actually was reliance is a fact issue left for another day.

Consumer Fraud Act

The defendant also moves to strike Count II of the complaint which makes a claim against the defendant based on violations of the Consumer Fraud Act (N.J.S.A. 56:8-1, *et.seq.*). The defendant Merck maintains that the plaintiff as a third party payor for its members is not a "consumer" under the statute and therefore not entitled to the protection offered by the statute.

There can be no disagreement that the purpose of the Consumer Fraud Act is the "protection of consumers by eliminating sharp practices and dealings in the marketing of merchandise." Channel Cos., Inc. v. Britton, 167 N.J.Super. 417, 417 (App.Div. 1979). Because it is a remedial act, it should be liberally construed to serve that goal. New Mea Const. Corp. v. Hayer, 203 N.J.Super. 486, 501-02 (App. Div. 1985). As the Supreme Court has stated "the history of the Act is one of constant expansion of consumer protection." Gennari v. Weichert Co. Realtors, 148 N.J. 582, 604 (1997).

N.J.S.A. 56:18-9 actually uses the word "person" not "consumer." The Act states that "any person who suffers an ascertainable loss of moneys or property, real or personal" may bring an action if the loss was caused by an unlawful practice or method. There is no dispute the word "person" is not limited to individuals or to those who purchase personal or household items. The word "consumer" is used with much more limited connotations in other acts. Both the Consumer

Credit Transaction Act, N.J.S.A. 56:11-1 and the Consumer Contract Act N.J.S.A. 56:12-1 limit the definition of "consumer" to an individual. The Consumer Fraud Act however uses the word "person" and includes business entities such as the plaintiff in this case.

In Marascio v. Campanella, 298 N.J.Super. 491 (App. Div. 1997), the Court held that a corporation purchasing goods or services generally sold to the public is a consumer entitled to the protection of the Act.

In Kavky v. Herbalife Intern. of America, 359 N.J.Super. 497 (App. Div. 2003), the Appellate Court applied the Act to the purchase of a franchise. The Court stated not to interpret the Act broadly would deny protection from "pyramid schemes and similar mass public frauds." Id. at 501

Although Kavky dealt with the meaning of the word "merchandise" under the Act, the Appellate panel in Kavky, supra, states they accept the definition of "consumer" set forth in Neveroski v. Blair, 141 N.J.Super. 365, 378 (App. Div. 1976). The Neveroski decision defined consumers as those who:

> "purchase products from retail sellers of merchandise consisting of personal property of all kinds or contract for services of various types brought to their attention by advertising or sales techniques."

In this case, the plaintiff paid for the purchase of the product from retail sellers. The plaintiff sustained the economic cost of the higher price for VIOXX®. The individual members retain their own individual claims for personal injury and the plaintiff doesn't seek compensation for that. The plaintiff seeks the added cost to the plaintiff that resulted from their reliance on alleged misrepresentations by the defendant. If their claim is true, then the plaintiff has suffered an ascertainable loss by paying for a retail product based on false advertising and "sharp practices" of the defendant. Certainly, this should be covered by the statute.

The defendants rely on City Check Cashing, Inc. v. Nat. State Bank, 244 N.J.Super. 304 (App. .Div. 1990) and Arc Networks v. Gold Phone Card Co., 333 N.J.Super.L. 587 (Law Div. 2000). In these cases, the plaintiffs were found not to be entitled to protection of the Consumer Fraud Act. Both these cases are distinguishable because they involve buyers of wholesale services to resell at retail. In the cases cited by the defendant the services purchased were not available to the general public which is completely different from the VIOXX® which was being marketed to the public by the defendant.

In the case of Zorba Contractors v. Housing Authority of Newark v. Georgia-Pacific Corporation, 282 N.J. Super. 430 (App. Div. 1995), the Court notes that the New Jersey statute is one of the strongest consumer protection laws in the country. The Court found the Housing Authority of Newark was unquestionably a consumer under the Act even when purchasing merchandise with public funds.

The issue of remoteness of proximate cause would be relevant only if the plaintiffs were claiming for cost of treating members for personal injuries caused by taking VIOXX®. In this case, this issue is not relevant. In fact, this plaintiff is the proper party to claim for the cost of paying an increased price because of the alleged misrepresentations that VIOXX® was safer and more effective than cheaper drugs on the market.

In the case of Desiano v. Warner Lambert, 326 F.3d 339 the U.S. Court of Appeals for the Southern District of New York found the New Jersey consumer Fraud Act did protect insurers who paid for the drug Resulin at a higher price than diabetes drugs on the market based on false advertising. The District Court had dismissed the claim based on proximate cause issues citing to Holmes v. Securities Investor Protection Corp., 503 U.S. 258 (1992) and Laborers Local 17 Health & Benefit Funds v. Phillip Morris, 191 F.3d 229 (2d Cir. 1999). These cases

dismissed actions based on lack of direct relationship between the injurious conduct and the injury. The Circuit Court in Disiano, supra, found these cases were distinguishable because they were RICO claims and because the plaintiff's damages were entirely derivative of injuries to their insured. In Disiano, supra, as in this case now before the Court, the claim is for direct financial losses sustained by the plaintiff as a result of the increased cost paid for the drug.

The Court in Desiano, supra, pointed out that if the plaintiff had paid substantially more for a drug falsely advertised as safer than Drug A when it was really identical to Drug A and just sold under a different name, there would be direct losses to the "person" or entity paying for the drug as a result of the false ads even if no person was actually injured by the drug.

The defendant focuses on a definition of consumer from the case of Hundred East Credit Corp. v. Eric Shuster Corp., 212 N.J.Super. 350 (App. Div. 1986). In that case, the Court described a consumer as "one who uses goods and so diminishes or destroys their utilities." This definition is quoted in City Check Cashing Inc. v. National State Bank, supra. In the Hundred East Credit Corp v. Shuster, supra, opinion, the Appellate Division rejected a narrow interpretation of "consumer." In that opinion, the language relied upon by defendants is taken from the Webster's Dictionary and does not express the outer limits of who is covered by the Act. In fact, the Court states:

> Nothing in that statutory language suggests that the Act is inapplicable to the sale of merchandise for use in business operations. To the contrary, the language on its face makes the Act applicable to all sales of 'merchandise' without regard to its intended use or the nature of the buyer. 212 N.J.Super. 350, at 355.

The Court finds that the limit placed by the defendants that a "person" under the Act must be the one who actually takes the medication or uses the product is too simplistic. The focus should be on a misrepresentation causing a "person" to pay for something they otherwise would not have been willing to pay for because of the higher cost. This fits the purpose of the Act. If,

for example, a "person" buys a gift for a third party based on false advertising, it does not matter that the person who is duped into making the purchase does not personally use the product.

The Court finds that the motion to dismiss the claim under the Consumer Fraud Act must be denied.

DATE OF DECISION: 07/09/04

/s/ Carol E. Higbee
CAROL E. HIGBEE, J.S.C.

XXXX Order is attached.

This decision will be posted on the judiciary website and can be viewed at http://www.judiciary.state.nj.us/decisions.htm for a period of six weeks from the motion return period.

TAB 4

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

IN RE Lorazepam & CLORAZEPATE ANTITRUST LITIGATION

MDL Docket No. 1290
Misc. No. 99mc0276

This Order applies to:

All Actions

MEMORANDUM OPINION

Pending before the Court are Defendants' Joint Motion for Summary Judgment for Failure to Establish Liability[1] [# 607], Defendants' Joint Motion for Summary Judgment for Failure to Establish Proximate Causation and Damages[2] [# 608], and Plaintiff Blue Cross Blue Shield of Minnesota's Motion for Partial Summary Judgment on Per Se Liability[3] [# 618]. Upon careful review of the parties' motions, *oppositions*, replies thereto, the various supplemental filings of both parties, and the entire record herein, the Court will deny the motions.

[1] Citations to Defendants' Joint Motion for Summary Judgment for Failure to Establish Liability are designated "Memo(L)."

[2] Citations to Defendants' Joint Motion for Summary Judgment for Failure to Establish Proximate Causation and Damages are designated "Memo(D)."

[3] Citations to Plaintiff Blue Cross Blue Shield of Minnesota's Motion for Partial Summary Judgment on Per Se Liability are designated "Per Se Memo."

I. BACKGROUND[4]

The background and procedural history in this case is quite extensive and has been presented in several other opinions. See, e.g., the following *In re* Lorazepam and Clorazepate Antitrust Litigation opinions: 289 F.3d 98 (D.C. Cir. 2002); 295 F. Supp. 2d 30 (D.D.C. 2003); 202 F.R.D. 12 (D.D.C. 2001).

Regarding the instant motions, Plaintiffs instituted this action alleging that Defendants entered into exclusive licensing agreements in restraint of trade in order to raise, maintain, and stabilize the prices for the generic drugs Lorazepam and Clorazepate, and that Defendants monopolized or attempted to monopolize the markets for Lorazepam and Clorazepate tablets and the active pharmaceutical ingredients ("API") used to manufacture these drugs. See, e.g., Complaint* ¶¶ 1, 4, 8, 20; Complaint ¶¶ 4, 9, 19. Plaintiffs have filed suit under Minnesota, *Massachusetts*, and Illinois state law on behalf of themselves as third party payors for prescription drugs for their insureds, and on behalf of certain unnamed nonparty customers, including employer-sponsored health plans, seeking to recover "the millions of dollars in overpayments for Lorazepam and Clorazepate" allegedly paid by Plaintiffs and the nonparties. Complaint* ¶ 1; Complaint ¶ 1. Plaintiffs allege that they paid for and absorbed *supra*competitive prices allegedly charged by Mylan by making reimbursements for Lorazepam and Clorazepate tablets pursuant to insurance contracts with employee benefit plans that provide prescription drug coverage to their members. Complaint* ¶¶ 7, 39; Complaint ¶¶ 9, 21.

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[4] For convenience, citations herein to the Second Amended Complaint of Plaintiffs BCBS Minnesota, Federated, and BCBS Massachusetts are accompanied by a "*." References to the Second Amended Complaint of Health Care Service Corporation ("HCSC") will not be noted with a "*."

A. *The Parties*

Plaintiffs Blue Cross Blue Shield ("BCBS") Minnesota, Federated Mutual Insurance Company ("Federated"), and BCBS Massachusetts (collectively, "BCBS Plaintiffs"), along with Plaintiff HCSC, are health insurance companies that are third-party payors for prescription drugs, including Lorazepam and Clorazepate, on behalf of their insureds and self-funded customers, typically employer-sponsored health plans that contract with Plaintiffs to administer claims in their behalf and pursue plan-related losses. Complaint* ¶¶ 13, 14, 15; Complaint ¶¶ 14. Plaintiffs are engaged in prescription drug managed care programs on behalf of their insureds and self-funded customers. Complaint* ¶¶ 13, 14, 15; Complaint ¶¶ 14.

Defendant Mylan Pharmaceuticals, Inc. ("Mylan") is a large generic drug manufacturer and distributor, marketing at least 91 generic drugs, including Lorazepam and Clorazepate. Memo(L) at 7; Complaint* ¶¶ 16, 17; Complaint ¶¶ 15, 16. Defendant Cambrex is a company engaged, through its subsidiaries, in the business of selling chemicals for, among other things, pharmaceuticals. Memo(L) at 7; *Complaint** ¶ 18; Complaint ¶ 17. Profarmaco, an Italian corporation that manufactures and sells API, is one of Cambrex's wholly owned subsidiaries. Id. Defendant Gyma Laboratories of America, Inc. ("Gyma") sells APIs and other chemicals to the pharmaceutical industry. Memo(L) at 7; Complaint* ¶ 19; Complaint ¶ 18. Gyma buys APIs from Profarmaco, including Lorazepam and Clorazepate API, and resells them to generic drug manufacturers in the United States. Id. Exclusive licensing agreements between Defendants are the key issues in this litigation.

B. *Pharmaceutical Industry*

1. *Supply Chain*

Mylan does not sell anything directly to Plaintiffs. SMF(D)[5] ¶ 2; GIF(D)[6] ¶ 2. Instead, Mylan generally sells to wholesalers and pharmacies. SMF(D) ¶ 3; GIF(D) ¶ 3. BCBS Plaintiffs contract with a pharmacy benefit manager ("PBM"), which in turn contracts with participating pharmacies. SMF(D) ¶ 4; GIF(D) ¶ 4. HCSC directly contracts with pharmacies. GIF(D) ¶ 4. Pharmacies sell prescription drugs to consumers, and then seek reimbursement for any remaining costs beyond the patient's co-payment or co-insurance payment from the patient's insurance company. SMF(D) ¶ 7; GIF(D) ¶ 7. Generally, the pharmacy would receive payment from the PBM, which in turn would bill the *insurer*, such as Plaintiffs. Id. The amount paid by Plaintiffs for a particular prescription reimbursement is set by formulas based on several fluctuating variables in their contracts with PBMs or pharmacies. GIF(D) ¶ 8.

2. *Regulatory Framework*

Before a manufacturer sells a prescription drug in the United States, regulatory approvals must be obtained. Memo(L) at 9; Complaint* ¶ 21; *Complaint* ¶ 23. A manufacturer of a generic version of a prescription drug may expedite FDA approval by filing an Abbreviated New Drug Application ("ANDA"), which relies on the safety and efficacy data filed with the FDA for the

[5] Citations to SMF(D) refer to Corrected Statement of Material Facts not in Genuine Dispute in Support of Defendants' Joint Motion for Summary Judgment for Failure to Establish Proximate Causation and Damages. Citations to SMF(L) refer to Corrected Statement of Material Facts not in Genuine Dispute in Support of Defendants' Joint Motion for Summary Judgment for Failure to Establish Liability.

[6] Citations to GIF(D) refer to Plaintiffs' Joint Statement of Genuine Issues of Material Fact Regarding Proximate Cause and Damages. Citations to GIF(L) refer to Plaintiffs' Joint Statement of Genuine Issues of Material Fact Regarding Liability.

bioequivalent pioneer drug. Memo(L) at 9; Complaint* ¶ 30; Complaint ¶ 27. The ANDA process may take from several months to two years or more. Id.

Every ANDA application filed for approval by a generic manufacturer must reference that application of an API supplier who has been previously approved by the FDA to supply the API for that drug product. Memo(L) at 9; Complaint* ¶ 34; Complaint ¶ 30. In order to obtain approval to sell API, an API supplier must file a Drug Master File ("DMF") with the FDA. Id. More than one drug manufacturer may reference the DMF of the same API supplier. Id. When a generic manufacturer changes to a new API supplier, it must file an ANDA supplement with the FDA, which includes a reference to the new API supplier's DMF and test results regarding the generic manufacturer's product using the new API.[7] Id. This process generally takes a minimum of twelve months. Id.

3. *Lorazepam and Clorazepate*

Lorazepam is the generic equivalent of Ativan® and Clorazepate is the generic equivalent of Tranxene®; both are prescription anti-anxiety drugs. SMF(L) ¶ 1; GHF(L) ¶ 1. Prior to the exclusive agreements, Profarmaco and Gyma supplied Lorazepam API and Clorazepate API to Mylan, as well as its generic competitors. Memo(L) at 10; Complaint* ¶ 35; Complaint ¶ 33.

C. *The Exclusive Agreements*

In November of 1997, Mylan and Profarmaco executed two agreements, each entitled "Exclusive Agreement," in which Profarmaco agreed to supply API, the active ingredient required to manufacture the drugs Lorazepam and Clorazepate, exclusively to Mylan in exchange for an

[7] This is assuming the manufacturer did not have regulatory approval for the new supplier's API already on file.

upfront payment and a share of Mylan's future profits from the sale of the two drugs in the form of royalty payments. Memo(L) at 10-11; Opp.(L)[8] at 4; Pl's Ex. 49, 50. The exclusive agreements, which each had a term of ten years, provided that Profarmaco would not supply Lorazepam or Clorazepate API to any other generic manufacturers in the United States, but did not prohibit sale to U.S. branded drug manufacturers or sale to any drug manufacturer outside the U.S. Id. However, the exclusive agreements also contained a provision that committed Profarmaco to take all steps reasonably necessary to prevent any API it manufactured or distributed sold outside of the U.S. from entering the territory. Pl.'s Ex. 49, 50. The agreements were terminated in December 1998, shortly after the Federal Trade Commission ("FTC") announced its investigation of Mylan's actions. Memo(L) at 11; Opp.(L) at 4.

II. LEGAL STANDARD FOR MOTIONS FOR SUMMARY JUDGMENT

A court may only grant summary judgment if "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 247 (1986) (quoting Fed. R. Civ. P. 56(c)). Summary judgment may not be granted where the evidence is such "that a reasonable jury could return a verdict for the nonmoving party." Id. at 248. The Court must view the evidence, no matter its persuasiveness, in the light most favorable to the non-movant and draw all reasonable inferences in its favor. Info. Handling Servs., Inc. v. Defense Automated Printing Servs., 338 F.3d 1024, 1032 (D.C. Cir. 2003) (quoting Waterhouse v. District of Columbia, 298

[8] Citations to "Opp.(L)" refer to Plaintiffs' Joint Opposition to Defendants' Joint Motion for Summary Judgment for Failure to Establish Liability.

F.3d 989, 991 (D.C. Cir. 2002); see also Washington Post Co. v. United States Dep't of Health and Human Servs., 865 F.2d 320, 325 (D.C. Cir. 1989) (quoting Popham, Haik, Schnobrich, Kaufman & Doty, Ltd. v. Newcomb Sec. Co., 751 F.2d 1262, 1263 (D.C. Cir. 1985) ("Any doubt is to be resolved against the moving party.").

III. GOVERNING LAW

Plaintiffs assert claims under the competition laws of Illinois, Minnesota, and Massachusetts. 740 Ill. Comp. Stat. Ann. § 10/7 (2004); Minn. Stat. § 325D.57 (2004); Mass. Gen. Laws ch. 93A §2(a) (2004). Illinois, Minnesota and Massachusetts all look to federal antitrust law for guidance in interpreting their own state competition laws. 740 Ill. Comp. Stat. § 10/11; Ciardi v. F. Hoffmann-La Roche, Ltd., 762 N.E.2d 303, 309 (Mass. 2002); Howard v. Minnesota Timberwolves Basketball Ltd. P'ship, 636 N.W.2d 551, 556 (Minn. Ct. App. 2001); see *In re* Lorazepam & Clorazepate Antitrust Litigation, 295 F. Supp. 2d 30, 37 (D.D.C. 2003).

IV. DISCUSSION

A. *Partial Summary Judgment for Per se Liability*

Plaintiff BCBS Minnesota asserts that partial summary judgment is warranted because Defendants' implementation of the exclusive agreements and Mylan's subsequent price increases constitute per se violations of the Minnesota Antitrust Law of 1971. Per se Memo at 8. Per se treatment is reserved for conduct that is so obviously anticompetitive that no inquiry into actual effects on the market is needed. See Northern Pac. Ry. v. United States, 356 U.S. 1, 5 (1958). BCBS Minnesota puts forward three distinct bases for finding the agreements to be per se antitrust violations under Minn. St. § 325D.53, subd. 1(3): (1) they constitute illegal vertical refusals to

deal; (2) they operate as vertical price-fixing measures; and (3) they are uniquely naked restraints on competition. Per se Memo at 9.

As to the first basis, the Supreme Court of Minnesota has held that an agreement is per se illegal under § 325D.53, subd. 1(3) only where the refusal to deal targets a specific third party. Minnesota-Iowa Television Co. v. Watonwan T.V. Improvement Ass'n, 294 N.W.2d 297, 307 (Minn. 1980) (contract provision that excluded "any station carrying ABC network programming" rather than targeting specific television station was not per se illegal as refusal to deal); Hough Transit, Ltd. v. National Farmers Organization, 472 N.W.2d 358, 361 (Minn. Ct. App. 1991). BCBS Minnesota struggles to distinguish Wantonwan by arguing that the exclusive agreements here have a more specific target than the agreement in Wantonwan. BCBS Minnesota asserts that the standard's specificity requirement is met because the exclusive agreements specifically target "any other North American generic manufacturers." Per se Memo at 11-12. The fact that the prohibition in the exclusive agreements may be more specific than the one in Wantonwan, a proposition that is itself tenuous, is not determinative. It is clear that the law requires an agreement to target a specific third party alone in order to be a per se violation of the statute. See McLaughlin Equip. Co., Inc. v. Servaas, 2004 WL 1629603 at *32 (S.D. Ind. 2004) ("[f]ollowing the reasoning of Wantonwan and Hough Transit, [the plaintiff] cannot withstand summary judgment on [its] refusal to deal claim under § 325D.53, subd. 1(3). [The plaintiff] has not shown that any agreement between [the defendants] referred specifically to [the plaintiff]."); see also Hough Transit, 472 N.W.2d at 361 ("[a]lthough that contract effectively is a refusal to deal with Hough, it also is a refusal to deal with every other milk hauler as well."). The general exclusivity provisions

in the agreements at issue in this case cannot be found to be per se illegal refusals to deal because they do not specifically target third parties.

BCBS Minnesota next argues that the agreements in this case are per se illegal under Minnesota's statute because they were effectively minimum resale price maintenance agreements. Per se Memo at 13. In order for a minimum resale price maintenance agreement to be per se unlawful, the agreement must require the distributor to adhere to specific prices. Business Elecs. Corp. v. Sharp Elecs. Corp., 485 U.S. 717, 735-36 (1988). Plaintiffs fail to provide evidence that Mylan made any promises to Profarmaco concerning its tablet prices. Defendants' Opposition to Plaintiff Blue Cross Blue Shield of Minnesota's Motion for Partial Summary Judgment ("Per se Opp.") at 11. Instead, BCBS Minnesota argues that the agreements are the "functional equivalent" of resale price maintenance agreements because they created a royalty system that required Mylan to pay a percentage of its net revenue to Profarmaco. Per se Memo at 13. BCBS Minnesota argues that the requirement of prepayment of these royalties effectively set a minimum price, because Mylan would have to set prices at a certain level in order to avoid having to recoup money from Profarmaco if the actual percentage of revenue owed turned out to be less than the prepayment. Id. However, that proposition is not supported by the law. Under the exclusive agreements, Mylan remained free to set its prices however it chose. There was no provision requiring Mylan to maintain a specific price or price level in its sales. Therefore, per se treatment of the agreements as illegal minimum resale price maintenance agreements is not warranted.

Finally, BCBS Minnesota argues that the agreements are per se unlawful under the Minnesota statute because they are "uniquely naked restraints." Per se Memo at 14. BCBS Minnesota argues that under Minnesota law, a finding of a per se violation is not limited to the

enumerated examples in § 325D.53; a court is free to find other per se violations where there is "egregiously anticompetitive behavior." Id. BCBS Minnesota's argument is that Defendants' conduct in this case was so outrageous, that it should be found to be a per se violation of Minnesota antitrust law. BCBS Minnesota does not articulate any support for such a finding in this case, other than the fact that the exclusive agreements had "significant anticompetitive effects." Id. In the per se arena, the relevant analysis is whether the particular conduct in question lacks any redeeming virtue. See White Motor Co. v. United States, 372 U.S. 253, 262 (1963). Here, the conduct at issue is Defendants' entering into exclusive supply agreements, followed by large price increases. Such conduct is not so uniquely anticompetitive as to make it a per se antitrust violation requiring no further analysis. To the contrary, the Supreme Court has recognized that non-price, vertical agreements, should be held unlawful only if they have a demonstrated anticompetitive effect in the market. Business Elecs., 485 U.S. at 724. Thus, per se treatment is inappropriate, and the motion for partial summary judgment is denied.

B. *Summary Judgment for Failure to Establish Liability*

Defendants argue that Plaintiffs' restraint of trade and monopolization claims cannot survive summary judgment because Plaintiffs have failed to demonstrate that the markets for Lorazepam or Clorazepate API were significantly foreclosed as a result of Defendants' actions. Because there were alternative sources of API sufficient to allow Mylan's competitors to bring Lorazepam and Clorazepate tablets to the market within one year, and the agreements terminated after only one year, any foreclosure was too brief to be actionable. Memo(L) at 31. Therefore, Defendants argue, summary judgment for failure to establish liability is appropriate in this case.

1. *Defining the Relevant Market*

Defining the relevant market is a prerequisite to a proper evaluation of Plaintiffs' claims. Geneva Pharmaceuticals Technology Corp. v. Barr Laboratories, Inc., 386 F.3d 485, 495-96 (2nd Cir. 2004). For Plaintiffs' monopolization claims, the crucial analysis of market power depends on the definition of the relevant market; additionally, for the restraint of trade claims, the competitive effects of an agreement must be measured against the relevant market. Geneva, 386 F.3d at 496 (citing, Copperweld v. Independence Tube Corp., 467 U.S. 752, 768 (1984) ("rule of reason requires 'an inquiry into market power and market structure designed to assess the combination's actual effect.'")). In Geneva, a case similar to ours, the Court of Appeals for the Second Circuit faced an antitrust suit between generic drug manufacturers alleging a conspiracy between a generic competitor and its supplier to monopolize and restrain trade. The court there found that the relevant market included only the generic versions of the drug, not the brand. Id.

In their complaints, Plaintiffs define the relevant markets as (1) the market for generic Lorazepam tablets approved for sale in the U.S. and sold in Illinois, New Mexico, and Texas ("the relevant states" collectively); (2) the market for generic Clorazepate tablets approved for sale in the U.S. and sold in the relevant states;(3) the market for Lorazepam API approved for sale in the U.S. and sold in the relevant states; and (4) the market for Clorazepate API approved for sale in the U.S. and sold in the relevant states. Complaint ¶ 19; Complaint* ¶ 20.

Defendants agree that the API supply markets are appropriate relevant markets. Memo(L) at 26. Defendants also state that for summary judgment purposes, they accept Plaintiffs' definition of the Lorazepam and Clorazepate tablet markets. Memo(L) at 25-26. However, Defendants characterize Plaintiffs' definition of the tablet markets as including the brands (contrary to the

allegations in the complaints), based on statements to this effect made by Plaintiffs' expert during his deposition. See SMF(L) ¶¶ 3, 8; Saha Rep.[1] at 12-26. Plaintiffs' position is that the relevant market does not include the brands, or at least that the generic drug manufacturers are in a "submarket" under antitrust case law. Opp.(L) at 12-16; Pl.'s Supp.(L)[2] at 9.

A relevant market is defined as all products "reasonably interchangeable by consumers for the same purposes." United States v. E.I. du Pont de Nemours & Co., 351 U.S. 377, 395 (1956). The appropriate market for antitrust analysis may also be a "submarket." Brown Shoe Co. v. United States, 370 U.S. 294, 325 (1962). Brown Shoe held that the definition of a submarket relies on a fact-intensive inquiry that considers factors such as recognition of the submarket as a separate economic entity, the product's peculiar characteristics and uses, unique production facilities, distinct customers, distinct prices, sensitivity to price changes, and specialized vendors. Id. An analysis of the Brown Shoe factors as related to the instant case is appropriate here. See Geneva, 386 F.3d at 495-500 (analyzing the Brown Shoe factors for purposes of reviewing trial court's grant of partial summary judgment in lawsuit alleging restraint of trade and monopolization of warfarin sodium market and concluding that generics alone constituted relevant market).

(a) *Price Differential*

It is undisputed that there is a marked price differential between generic Lorazepam and Clorazepate and their brand equivalents: prior to the exclusive agreements, Lorazepam and Clorazepate had reached pricing levels below two percent of the branded equivalents. SMF(L) ¶

[1] Citations to "Saha Rep." refer to the Expert Report of Dr. Atam Saha, dated April 19, 2004, located at Plaintiffs' Exhibit 86.

[2] Citations to "Pl.'s Supp.(L)" refer to Plaintiffs' Joint Motion for Leave to File Supplemental Authority, or in the Alternative, Sur-reply to Defendants' Reply Memorandum in Support of Defendants' Joint Motion for Summary Judgment for Failure to Establish Liability [# 647].

13; GIF(L) ¶ 13. Defendant Mylan's pricing charts reveal that in the ten years prior to the exclusive agreements, the price of generic Clorazepate decreased while the brand more than doubled in price; the price of generic Lorazepam remained relatively stable while the brand similarly more than doubled in price. See Opp.(L) at 17 n.16. This evidence of a substantial gap in pricing between the generics and the brands is indicative of separate markets. See Geneva, 386 F.3d at 496-97 (finding generic's pricing at fifty percent of brand indicative of a distinct customer group with brand allegiance and/or high risk sensitivity that was unwilling to switch from the known brand even in the face of a discounted alternative).

(b) *Inelastic Demand*

Given the substantial price differential between the generics and their brand equivalents, and the Defendant's pricing charts that indicate that even though the price of the generics were but a fraction of those of the brands, the brands were able to more than double their prices in the ten years before the agreements at issue here, there is strong evidence that the brands enjoyed an inelastic demand in this case. See Id. at 497-98.

(c) *Regulatory Influences*

Further evidence that generic Lorazepam and Clorazepate tablets compete in a separate market from their brand equivalents is found in the many state pharmacy regulations that require or permit pharmacists to substitute the generic form of a drug for the brand without obtaining permission of the treating physician. See 225 Ill. Comp. Stat. 85/25 (2001); N.M. Stat. Ann. § 26-3-3 (2001); Mass. Gen. Laws Ch. 112 § 12D (2000); Minn. Stat. § 151.21 (2000); Tex. Occ. Code Ann. § 562.008 (2000). These statutes limit the brands' ability to win market share away from the

generics, further evidence that the brands do not compete in the same market as the generic manufacturers.

(d) *Industry Recognition*

The Geneva court found that in the warfarin sodium market, "generic manufacturers treat each other as the entities which most directly affect their pricing and output decision," 386 F.3d at 498. Similarly, in the instant case, Plaintiffs point to Mylan's own employees' deposition testimony that in setting the prices of their generic products, the relevant consideration were the other generic manufacturers, not the brands. See Opp.(L) at 17-18; Stern Rep.[3] at 37; Mauro 10/12/1998 Dep. at 82 (Pl.'s Ex. 114). Additionally, the director of sales and marketing for the generic division of a competing generic manufacturer testified that the brand version of Lorazepam was not considered a competitor because of the significant erosion of the brand price in the generic market. Hartman 6/29/2000 Dep. at 51 (Pl.'s Ex. 102). This testimony suggests that the industry recognized that generic Lorazepam and Clorazepate tablets constituted markets separate from those of their branded counterparts.

Based on the foregoing analysis of the Brown Shoe factors, the totality of the evidence in this case strongly suggests that the generic manufacturers' decisions on pricing and output were restrained by the market forces caused by competition between the generics, not the brands. Therefore, Plaintiffs have at the very least raised a genuine dispute of material fact as to whether the relevant tablet markets in this case include the brands. See Geneva, 386 F.3d at 500 (holding that the relevant market for purposes of evaluating Plaintiffs' antitrust claims was the generic

[3] Citations to "Stern Rep." refer to the Expert Report of Craig S. Stern, Pharm. D., MBA, located at Pl.'s Ex. 85.

tablet market, based on evidence that strongly suggested competition among generics as restraint on single generic competitor's pricing or output).

2. *Restraint of Trade Claims*

Plaintiffs allege that Defendants unlawfully restrained trade and conspired to unlawfully restrain trade in violation of the competition laws of Illinois, Massachusetts, and Minnesota. See 740 Ill. Comp. Stat. Ann. § 10/7 (2004); Mass. Gen. Laws ch. 93A §2(a) (2004); Minn. Stat. § 325D.57 (2004). Because the conduct in this case does not fall into the narrow category of behavior so manifestly adverse to competition that it is illegal per se, this case will be evaluated under the rule of reason. F.T.C. v. Indiana Fed'n of Dentists, 476 U.S. 447, 459 (1986). Under the rule of reason, Plaintiffs bear the initial burden of establishing that a restraint (in this case, the exclusive agreements and subsequent price increase) had an actual and substantial adverse effect on competition in the market. See, e.g., United States v. Arnold Schwinn & Co., 388 U.S. 365, 374-375 (1967), overruled on other grounds by Continental T.V., Inc. v. GTE Sylvania Inc., 433 U.S. 36, 58-59 (1977).

The allegedly injurious exclusive agreements in this case were vertical, nonprice agreements. Typical indicators of an exclusive dealing arrangement's adverse effect on competition are higher consumer prices, decreases in the output of existing manufacturers, decreased entry by competitors, and/or increased difficulties to entry. Saha Rep. at 18; see Geneva, 386 F.3d at 508. Exclusive dealing is an unreasonable restraint of trade only when a significant fraction of buyers or sellers are frozen out of the market by the exclusive arrangement. Geneva, 386 F.3d at 508; Minnesota Ass'n of Nurse Anesthetists v. Unity Hospital, 208 F.3d 655, 661 (8th Cir. 2000) (quoting Jefferson Parish Hosp. Dist. No. 2 v. Hyde, 466 U.S. 2, 45 (1984)

(O'Connor, J., concurring). Defendants argue that the exclusive agreements did not cause significant foreclosure in the relevant market, thus Plaintiffs' restraint of trade claims cannot survive summary judgment. In order to properly consider Defendants' claims, the Court must consider the competitive characteristics of the relevant markets in this case. See Geneva, 386 F.3d at 508.

(a) *Lorazepam*

Prior to the exclusive agreements, there were six generic manufacturers with approved ANDAs for generic Lorazepam tablets: Mylan, Purepac, Watson, Geneva, Danbury/Schein, and Mutual.[4] Opp.(L) at 21; Saha Rep. at Ex. 11. Mylan had more than twice the market share (38.3%), compared to its major competitors, Watson (17.5%) and Purepac (18.6%). Id. Purepac, Watson, and Mutual, along with Mylan, relied on Profarmaco for their API supply. The only active generic manufacturer that did not depend on Profarmaco API was Geneva, which had a market share of only 1.6 percent. Id. According to Plaintiffs' expert, the combined market share of generic manufacturers that relied on Profarmaco Lorazepam API was 74.4 percent. The remaining three manufacturers constituted only 7% of the market. Opp.(L) at 21; Saha Rep. at 20.

1. *Purepac*

After Purepac's supply of Profarmaco API was interrupted by the execution of the exclusive agreements, it looked to FIS/SST as an alternate supplier. FIS/SST would not supply Purepac because one of its customers had "already agreed to take all the FIS production of Lorazepam for this year." Opp.(L) at 23; Pl's Ex. 65. Purepac also unsuccessfully attempted to obtain API from Mylan, but Mylan refused. Opp.(L) at 24;Roman 8/12/2004 Dep. at 84-85, 87.

[4] Schein and Mutual had approved Lorazepam ANDAs but were not active in the market in 1997. Saha Rep. at Ex. 11.

(Pl.'s Ex. 122). Although Purepac was waiting to hear from another potential supplier, it predicted that it would be frozen out of Lorazepam API supply for the rest of 1998. Opp.(L) at 23; Pl.'s Ex. 65. As a result, Purepac notified its valued customers of an "abrupt and unanticipated raw material interruption" and discontinued its supply of Lorazepam tablets to those customers. Pl.'s Ex. 20. Purepac took steps to make its remaining supply last longer, and implemented price increases far above its prior pricing levels. Opp.(L) at 24; Pl.'s Ex. 20.

2. *Watson*

Prior to the exclusive agreements, Profarmaco supplied the API for Watson's Lorazepam tablets. Subsequent to the execution of the agreements, Watson was forced to find an alternate supplier for its API. Watson attempted to obtain API from SST/FIS, but the order was initially rejected because Watson had not purchased from that supplier in quite a while. Opp.(L) at 22; Beideman 6/13/2000 Dep. at 30-32 (Pl.'s Ex. 91). When FIS/SST did eventually offer Watson a price quote on Lorazepam API, the price was prohibitively high. According to Watson, the price was so high that, "it's almost as if that, you know, that they are not selling to us." Opp.(L) at 23; Chow 6/14/2000 Dep. at 240 (Pl.'s Ex. 97). The offered price was $125,000 per kilo or more, when Watson had been paying $500 to $550 per kilo for Lorazepam API before the agreements. GIF(L) ¶ 35; Chow 6/14/2000 Dep. at 239-240 (Pl.'s Ex. 97).

3. *Geneva*

After Geneva lost its Profarmaco API, it turned to FIS/SST for supply as well. It obtained Lorazepam API from SST at $150,000 per kilo, compared to the $775 price before the exclusive agreements. Opp.(L) at 24; Murray 12/16/1999 Dep. at 201-205 (Pl.'s Ex. 115). Because SST was now the only supplier to the generic marketplace other than Mylan, it was able to base its price on

the new finished dose price that resulted from Mylan's huge price increase. Opp.(L) at 24; Murray 12/16/1999 Dep. at 206-210 (Pl's Ex. 115).

Defendants argue that because Mylan's competitors were actually able to obtain alternative API supply within one year of the exclusive agreements, there was no foreclosure and thus no antitrust violation. However, the foregoing evidence presented by the Plaintiffs demonstrates a detrimental impact on the ability of Mylan's rivals in the generic Lorazepam tablet market to compete as a result of the exclusive dealing arrangement. While Mylan's competitors may have eventually obtained an alternative supply of Lorazepam API after the implementation of the exclusive agreements, the fact that cannot be ignored is Plaintiffs' evidence that they were only able to do so at a price increase of approximately 3000 percent. Contrary to Defendants' characterizations, this does not constitute an "unfettered" supply of API. What is not to be confused are two different issues: foreclosure and response to foreclosure. Declaration of Dr. Atanu Saha at 9. In this case, upon execution of the exclusive agreements, Mylan's active generic competitors that relied on Profarmaco API were immediately foreclosed. According to Plaintiffs' expert, upon execution of the exclusive agreements, at least 74.4 percent of the Lorazepam market was foreclosed. Saha Rep. at Ex. 11. Plaintiffs' have proffered evidence that Mylan gained market share while the exclusive agreements were in effect, despite its significant price increase. Saha Rep. at 23. This evidence suggests that the subsequent responses of Mylan's competitors were unable to discipline Mylan's pricing. Plaintiffs have presented evidence that the exclusive agreements did result in a significant degree of foreclosure in the generic Lorazepam tablet market.

(b) *Clorazepate*

In 1997, at the time of the exclusive agreements, there were four active generic manufacturers of Clorazepate: Mylan, Watson, Geneva, and Lederle.[5] Opp.(L) at 25; Saha Rep. at 16. Mylan had the largest share of the market at 68.2 percent, followed by Watson with 13 percent. Geneva and Lederle had only 0.1 percent and 0.2 percent market shares, respectively. Id. All of the active Clorazepate manufacturers were supplied with Profarmaco API. Id.

As a result of the exclusive agreements, Profarmaco/Gyma terminated its supply of Clorazepate API to Watson. Opp.(L) at 26. Watson was forced to locate an alternate API supplier, and contacted both Sanofi and Abbott as potential suppliers. However, regulatory requirements added significant delays to Watson's ability to market a product using API from either of those alternate suppliers. Id. Sanofi did not have the requisite DMF for Clorazepate, creating a lag time on Watson getting a finished good to market of "about nine to twelve months plus how long the manufacturer will take to get the approval." Opp.(L) at 26; Chow 9/25/1998 Dep. at 45 (Pl.'s Ex. 96). Watson did sign a contract with Abbott, the brand manufacturer, through which it obtained finished Clorazepate tablets, with the option to buy the API. Opp.(L) at 26; Pl.'s Ex. 102. Watson expected it would take up to two years to qualify Abbott API for its production. Opp.(L) at 26; Pl.'s Ex. 91. This evidence strongly suggests that Watson, Mylan's only real competitor on this product, was effectively frozen out of Clorazepate API supply by the exclusive agreements.

In addition to Plaintiffs' evidence that the exclusive agreements effectively foreclosed a significant percentage of both the Lorazepam and Clorazepate tablet markets, Plaintiffs have also proffered evidence that the agreements otherwise harmed competition in those markets. As stated

[5] Alra and Able also had ANDAs approved for Clorazepate, but were not active in the market in 1997. Saha Rep. at Ex. 13.

earlier, typical indicators of an exclusive dealing arrangement's adverse effect on competition are higher consumer prices, decreases in the output of existing manufacturers, decreased entry by competitors, and/or increased difficulties to entry. See Geneva, 386 F.3d at 508. Plaintiffs have proffered evidence that the exclusive agreements in this case had several of these effects on the relevant markets: prices to consumers increased, total unit sales of Lorazepam and Clorazepate tablets continued to decline, and the ability of Mylan's rivals to compete effectively with Mylan was significantly constrained. See, e.g., Saha Rep. at 18-26. Plaintiffs' proffer is sufficient to satisfy their initial burden under the rule of reason.

(c) *Pro-competitive Justification*

Under the rule of reason, the burden next shifts to Defendants to offer pro-competitive justifications for the arrangement. See Geneva, 386 F.3d at 509. Defendants argue that Mylan's decisions to increase prices on Lorazepam and Clorazepate tablets, and to enter into the exclusive agreements, were based upon independent business incentives. Memo(L) at 34. Defendants maintain that Mylan decided to raise prices on the two drugs, along with about a dozen others, because they were older products that were selling at only a small fraction of the brand price. Memo(L) at 4 n.2. Mylan decided to increase the price of these drugs to about fifty percent of the brand price. Id. Defendants submit that independent of this pricing decision, Mylan entered into the agreements with Profarmaco in November 1997 in order to secure a long term and stable source of API, to protect itself against the possible loss of supply by reason of vertical integration with other companies, and to incentivize Profarmaco to continue producing these older, low-margin products. Id.; Roberts Rep.[6] at ¶¶ 115-123.

[6] Citations to Roberts Rep. refer to the Expert Report of Dr. Gary Roberts, dated May 21, 2004.

Defendants submit that the agreements in this case had pro-competitive justifications in that they were simply a means to secure stable supply and resulted in increased competition because more manufacturers entered the market during the term of the agreements. The essential facts behind Defendants arguments, however, are in dispute. Plaintiffs submit that there is no evidence of any actual or threatened supply problems prior to the agreements. Opp.(L) at 42 (citing Roman, Stupar, Sanzen, and Puskar depositions); see also SMF(L) ¶ 5, 11. Plaintiffs have also proffered evidence that Lorazepam and Clorazepate were not unprofitable prior to the exclusive arrangement. GIF(L) ¶ 12. Further, Plaintiffs argue that there are no efficiency justifications since there were no reductions in transaction costs, and prices to consumers went up. Opp.(L) at 43; Saha Rep. at 18-20. Finally, integral to an evaluation of Defendants' pro-competitive justifications is the degree to which alternative API supply was available to allow Mylan's rivals to compete effectively, a fact which as previously discussed, is in dispute. See Geneva, 386 F.3d at 509.

(d) *Duration*

Defendants argue that the period in which the exclusive agreements were in effect was too brief to significantly harm competition and thus implicate an antitrust violation. Even accepting for the sake of argument that the impact of the exclusive agreements lasted only one year, this fact would not be dispositive. Defendants cite Williamsburg Wax Museum, Inc. v. Historic Figures, 810 F.2d 243 (D.C. Cir. 1987), for the proposition that where a supply agreement is challenged as exclusive, there can be no antitrust violation if alternative supply is available to competitors in the downstream market within one year. Memo(L) at 26. A fair reading of that case, however, does not deliver such a rule. First, the court was looking at duration of exclusivity in that case in its

analysis of monopoly power in the plaintiff's Section 2 monopolization claim, not with respect to restraint of trade. Williamsburg Wax, 810 F.2d at 252. The court refused to find monopoly power based on the sole fact that the defendant was the only available supplier for a period of less than one year. Id. The court did not hold that an antitrust claim based on foreclosure is barred as a matter of law anytime there is alternative supply available within one year. Second, in affirming the trial court's dismissal of plaintiff's restraint of trade claim in that case, the court did not base its decision on the existence of alternate supply, but rather on the fact that plaintiff had failed to support its allegations that the defendants unreasonably restrained trade with any concrete evidence. Id. at 253.

Defendants' focus on the duration of the exclusive agreements is misplaced. The relevant analysis is as to the duration of the effects of the agreements on the relevant markets, not simply the effective term of the agreements themselves. Geneva, 386 F.3d at 509-10. As Defendants themselves point out in their brief, what is relevant is the arrangement's actual effects on the market. Memo(L) at 11 (citing Microsoft, 253 F.3d at 59). The essential facts as to the duration of the actual effects of the exclusive agreements are in dispute. Plaintiffs have provided evidence to suggest that the agreements have negatively impacted competition in the relevant markets long after the agreements' termination, affecting prices in the market even today. See, e.g., Saha Rep. at 35-36. "The assessment of long-term effects depends greatly on the credibility of the evidence, which is the task of the jury." Geneva, 386 F.3d at 510. Plaintiffs' restraint of trade claims must be decided be the trier of fact.

2. *Monopolization Claims*

Plaintiffs allege that Defendants monopolized the markets for Lorazepam and Clorazepate,

and attempted to do so. Defendants claim that the undisputed facts demonstrate that Defendants lacked the monopoly power necessary to support Plaintiffs' monopolization and attempted monopolization claims. Memo(L) at 37.

(a) *Exclusionary Conduct*

Monopolization and attempted monopolization claims require proof of exclusionary conduct. Microsoft, 253 F.3d at 58 (quoting United States v. Grinnell Corp., 384 U.S. 563, 571 (1968)). Defendants first argue that Plaintiffs have failed to provide evidence of exclusionary conduct by Defendants. Memo(L) at 37-38. As discussed earlier, Plaintiffs have proffered evidence that Defendants' entrance into exclusive agreements resulted in significant foreclosure in the Lorazepam and Clorazepate markets.

(b) *Market Share*

Defendants argue that Mylan's market share in the Lorazepam market was so low that no reasonable jury could find that Mylan had monopoly power.[7] Memo(L) at 38. Defendants cite a number of cases for the proposition that market share must be greater than a bare majority in order for a monopolization claim to be actionable. Id. However, as Plaintiffs correctly point out, these cases hold that a market share of 50% or less alone does not establish a prima facie case of monopoly power, not that such a share precludes a finding of market power if other factors, such as significant barriers to entry, are present.[8] Opp.(L) at 32; see Broadway Delivery Corp. v. United Parcel Serv. of Am., Inc., 651 F.2d 122, 130 (2nd Cir. 1981) (holding that the district court

[7] Plaintiff's expert calculated Mylan's Lorazepam market share to be 38.3% in 1997 and 41% in 1998. Mylan's Clorazepate share was 68.2% in 1997, and increased almost 4% in 1998.

[8] See Blue Cross & Blue Shield of Wisconsin v. Marshfield Clinic, 65 F.3d 1406, 1411 (7th Cir. 1995) ("Fifty percent is below any accepted benchmark for inferring monopoly power from market share."); U.S. Anchor Mfg., Inc. v. Rule Industries, Inc., 7 F.3d 986, 1000 (11th Cir. 1993) ("we have discovered no cases in which a court found the existence of actual monopoly established by a bare majority share of the market.").

erroneously precluded a finding of monopoly power based on the defendants' market share of less than 50% because "the trend of guidance from the Supreme Court and the practice of most courts endeavoring to follow that guidance has been to give only weight and not conclusiveness to market share evidence."), cert. denied, 454 U.S. 968 (1981); see also Tops Mkts. Inc. v. Quality Mkts. Inc., 142 F.3d 90, 99 (2d. Cir. 1998) ("We cannot be blinded by market share figures and ignore marketplace realities, such as the relative ease of competitive entry."); Hayden Pub. Co. v. Cox Broad. Corp., 730 F.2d 64, 69 n.7 (2d. Cir. 1984) ("[A] party may have monopoly power in a particular market, even though its market share is less than 50%.").

Finally, Defendants do not even contend that this argument applies in the Clorazepate context, as, according to Plaintiffs' expert's report, Mylan's share of the Clorazepate market in 1997 was 68.2%. Saha Rep. at Ex. 13.

(c) *Barriers to Entry*

Defendants next argue that there were low barriers to entry in the relevant markets while the agreements were in effect; therefore, Mylan could not have had monopoly power as a matter of law. Memo(L) at 39. Defendants rely upon Microsoft, 253 F.3d at 82, for the proposition that without significant barriers to entry, a firm cannot possess monopoly power. See Reply(L) at 12. Plaintiffs submit that the costs and delays of the FDA regulatory process constitute high barriers to entry in the generic drug industry. Opp.(L) at 36. Plaintiffs' expert's report describes these heavy costs and delays. Saha Rep. at 4-6. For example, in the API markets, a supplier could only enter the market if it were properly qualified with the FDA through the DMF. Further, any potential buyer would have to have previously referenced that supplier's DMF with the FDA. Similarly, for the generic tablet markets, a drug manufacturer can only enter the market once it has obtained FDA

approval of its ANDA, has its ANDA actively on file, and has an API supplier that is properly qualified through the DMF. Id. Entry on both sides can be delayed by the lack of FDA approval, a process which takes a median time of 18 months up to as long as two or more years. Opp.(L) at 41-42. Courts have recognized that the FDA approval process can create high barriers to entry. See, e.g., Ortho Diagnostic Sys. v. Abbott Labs., Inc., 822 F.Supp. 145, 148 (S.D.N.Y. 1993) ("this market power is reinforced by high barriers to entry into the market . . . , including . . . obtaining FDA approvals."). The D.C. Circuit has recognized that other regulatory requirements may constitute barriers to entry. See Microsoft, 253 F.3d at 51; Southern Pac. Comm. Co. v. American Telegraph & Telegraph Co., 740 F.2d 980, 1001 (D.C. Cir. 1984), cert denied, 470 U.S. 1005 (1985) ("[T]he costs and delays of the regulatory process clearly constitute barriers to entry."). "Any market condition that makes entry more costly or time-consuming and thus reduces the effectiveness of potential competition as a constraint on the pricing behavior of the dominant firm should be considered a barrier to entry." Id. The FDA approval process is such a market condition in this case, and thus, may be considered a barrier to entry.

Defendants argue that the undisputed facts establish, however, that FDA approval was no barrier to entry in this case, because Mylan's competitors had pre-existing FDA approval to market the drugs using API from manufacturers other than Profarmaco. Memo(L) at 40. The existence of a competitor does not necessitate a finding that there were not high barriers to entry in the relevant markets. The defendants also point to the fact that it was possible for generic Lorazepam and Clorazepate manufacturers to circumvent the FDA approval process by entering into authorized generic arrangements with one of the brands, which were unaffected by the exclusive agreements.[9]

[9] Wyeth purchased its API from Technochemie, while Abbott manufactured its own supply of API.

Memo(L) at 40-41. Through these arrangements, which are only available at the price and discretion of the brand manufacturers, the generic manufacturer purchases a re-labeled version of the finished brand tablets, and then sells those tablets as their own. The generic manufacturer may enter the tablet market without any regulatory delay. Memo(L) at 10. However, a generic manufacturer participating in such an arrangement is still not getting API to manufacture its own tablets. The availability of the authorized generic arrangement does not mandate a finding that there were only low barriers to entry in the relevant markets at issue here. Plaintiffs have raised a genuine issue of material fact as to whether there were high barriers to entry in this case.

(d) *Other indicators of monopoly power*

In analyzing whether monopoly power exists, courts may consider "structural evidence" such as relative size and strength of the defendant, fluctuations in the defendant's market share, development of the industry, ease of entry, excess capacity, evidence of monopoly profits, and the impact of regulations. 2 Von Kalinowski, Antitrust Laws and Trade Regulations § 25.03(3) (2004), citing Pastore v. Bell Tel. Co., 24 F.3d 508 (3rd Cir. 1994). As the foregoing discussion demonstrates, Plaintiffs have proffered evidence that Defendants engaged in exclusionary conduct through their exclusive arrangement, that Mylan possessed a significant market share in both the Lorazepam and Clorazepate markets, and that there were high barriers to entry in the relevant markets. Plaintiffs have also provided evidence that Mylan's size and stature in the market gave it unique power over price, another indicator of monopoly power. Mylan acknowledged that it is the leading producer of generics in terms of the number of prescriptions filled. Opp.(L) at 44; Roman 2/17/2004 Dep. at 30 (Pl.'s Ex. 121). Watson's strategy in response to the effects of the exclusive agreements after obtaining supply from Abbott was to "be a participant and follower of the Mylan

strategy." Opp.(L) at 44; Wilkinson 6/28/2000 Dep. at 89 (Pl.'s Ex. 133). Watson adopted this strategy because Mylan was a much larger company and Watson was not able to go "toe to toe with Mylan." Id. Finally, Plaintiffs' evidence suggests that Mylan had the ability to control prices in the relevant markets, given that Mylan was able to raise prices upwards of 2000% and maintain them at or near those prices without losing market share. Opp.(L) at 39-40. Monopoly power is the power to control prices or exclude competition. United States v. E.I. duPont de Nemours & Co., 351 U.S. 377, 391 (1956). Plaintiffs have raised a genuine dispute of material fact as to whether Defendants possessed monopoly power in this case; therefore, their monopolization claims must be decided by the trier of fact.

(e) *Attempted Monopolization Claims*

Finally with regard to the monopolization claims, Defendants make a standing argument that Plaintiffs may not bring their attempted monopolization claims because they did not compete with Defendants in the relevant markets. Memo(L) at 38 n.8 (citing In re Air Passenger Computer Reservation Sys., 727 F.Supp. 564, 568-69 (C.D. Cal. 1989)). Plaintiffs correctly point out that this Court has already ruled that Plaintiffs have standing to pursue all of their claims. *In re Lorazepam & Clorazepate Antitrust Litigation*, 295 F. Supp.2d 30, 43 (D.D.C. 2003). No new evidence has come to light that warrants a revisit to the issue of standing at this time.

3. *Unjust Enrichment Claims*

Last, Defendants argue that Plaintiffs' unjust enrichment claims must fail because they are predicated on the antitrust claims and because Plaintiffs are barred from pursuing equitable remedies. Memo(L) at 43. To state a claim for unjust enrichment, Plaintiffs must establish that: (1) they conferred a legally cognizable benefit upon Defendants; (2) Defendants possessed an

appreciation or knowledge of the benefit; and (3) Defendants accepted or retained the benefit under inequitable circumstances. *In re* Lorazepam & Clorazepate Antitrust Litig., 295 F. Supp. 2d at 50. Defendants' argument is that Plaintiffs have failed to establish any violations of the antitrust laws, thus there are no "inequitable circumstances" to satisfy the third element of their unjust enrichment claim, and this claim too must fail. As has already been discussed, Plaintiffs' have provided evidence that the Defendants' actions constituted antitrust violations, therefore the unjust enrichment claims survive summary judgment as well.

Secondly, Defendants argue that Plaintiffs are barred from pursuing equitable remedies. Memo(L) at 44. Defendants assert that equitable remedies are not available where a legal remedy is also available. In this case, legal remedies are available and asserted by Plaintiffs to redress alleged acts committed by Defendants. Therefore, Defendants argue, Plaintiffs may not sustain an action for unjust enrichment. Memo(L) at 44-45. Plaintiffs seek an equitable recovery as an alternative to a legal remedy, and ask that the issue be considered after the evidence has been presented at trial.[10] Opp.(L) at 57. If the Court then determines that the legal remedy is inadequate under the controlling legal standard, it may submit an instruction to the jury on Plaintiffs' unjust enrichment claims as an alternate source of recovery. Id. In order to preclude the granting of equitable relief, "'an available remedy at law must be plain, clear and certain, prompt or speedy, sufficient, full and complete, practical, efficient to the attainment of the ends of justice, and final.'" Interstate Cigar Co. v. United States, 928 F.2d 221, 223 (7th Cir. 1991) (quoting 27 Am. Jur. 2d Equity § 94 (1966)). The mere existence of a possible remedy at law will not itself warrant a

[10] "[I]t is axiomatic that a court should determine the adequacy of a remedy in law before resorting to equitable relief." Franklin v. Gwinnett County Public Sch., 503 U.S. 60, 75-76 (1992).

denial of equitable relief. Interstate Cigar, 928 F.2d at 223 (citing American Life Ins. Co. v. Stewart, 300 U.S. 203, 214 (1937). Plaintiffs' unjust enrichment claims may proceed.

Based on the foregoing discussion, Defendants' Joint Motion for Summary Judgment for Failure to Establish Liability is denied.

C. *Summary Judgment for Failure to Establish Causation and Damages*

Defendants assert that there is no direct, causal link between Plaintiffs' alleged damages and Defendants' conduct. Defendants' Joint Motion for Summary Judgment for Failure to Establish Proximate Causation and Damages ("Memo(D)") at 3. Defendants argue that Plaintiffs' alleged damages are based on their reimbursement levels for Lorazepam and Clorazepate, and that those levels are unrelated to Mylan's prices, therefore Plaintiffs are unable to establish proximate causation, an essential element of their claims. See Lorazepam & Clorazepate Antitrust Litig., 295 F. Supp. 2d at 36 ("health services organizations attempting to recoup increased health care costs arising from alleged anticompetitive conduct must establish specific antitrust injury and proximate causation"). Defendants further argue that Plaintiffs' calculation of damages is impermissibly speculative because it fails to provide a rational basis on which to calculate damages that isolate the harm caused by Defendants' alleged misconduct from that caused by other forces. Memo(D) at 5. For both these reasons, Defendants argue, summary judgment is warranted.

1. *Proximate Causation*

Defendants first argue that there is no direct causal relationship between Defendants' alleged misconduct and Plaintiffs' increased reimbursement costs. Memo(D) at 3. Plaintiffs' allege injury based on the increase in reimbursement rates for Lorazepam and Clorazepate tablets caused by Defendants' unlawful conduct. Complaint ¶ 72; Complaint* ¶ 109. Defendants argue

that Plaintiffs' reimbursement rates are set by contracts negotiated with Pharmacy Benefit Managers ("PBMs") and pharmacies, and that these rates are unrelated to the prices at which Mylan sold its Lorazepam and Clorazepate tablets. Memo(D) at 4. Defendants point to the undisputed fact that Plaintiffs' reimbursement rates remained relatively constant, and at times increased, as Mylan's sale prices were falling after the termination of the exclusive agreements as conclusive evidence that there is no relationship between Mylan's pricing and Plaintiffs' costs. Id. Defendants assert that the dramatic reimbursement rate increases imposed by PBMs and pharmacies caused Plaintiffs' injury, wholly independent of Defendants' actions or Mylan's sales price. Memo(D) at 14.

The issue is whether the facts are undisputed that there is no causal connection between Defendants' conduct and Plaintiffs' injuries. That is not the case here. Plaintiffs have presented evidence that Defendants' actions did impact Plaintiffs' costs. As this Court has previously found, "Although the physician prescribes, the pharmacist dispenses, and the patient takes the medication, in most cases, *it is the insurer such as Plaintiffs who actually pay*," In re Lorazepam & Clorazepate Antitrust Litig., 295 F. Supp. 2d at 40 (emphasis original). When Plaintiffs are responsible for covering the cost of a patient's prescription, the amount Plaintiffs pay for that prescription is based upon a formula set by contracts Plaintiffs have negotiated with their PBMs or pharmacies. SMF(D) ¶ 8; GIF(D) ¶ 8. According to these formulas, Plaintiffs' reimbursement rates are generally the lesser of: (1) a discount off the published average wholesale price ("AWP"); (2) the pharmacy's usual and customary ("U&C") price; or (3) the maximum allowable cost ("MAC"). SMF(D) ¶ 21; GIF(D) ¶ 10. Defendants argue that Mylan's pricing has no affect on any of the variables in these formulas; however, Plaintiffs have presented evidence to the contrary.

While it is undisputed that AWP prices are not set directly by Mylan but published by independent information services, whether Mylan's pricing has an impact on AWP prices is indeed in dispute. SMF(D) ¶ 22; GIF(D) ¶ 22. Even a website cited by Defendants explains that the formula for determining AWP is based in part on the manufacturers' (e.g. Mylan's) published price for a drug product. See SMF(D) at Tab 38. Additionally, Plaintiffs have presented evidence that Mylan made a practice of notifying the AWP information services of its price adjustments, and statements made by Mylan employees in these notifications appear to acknowledge that Mylan's price increase would result in an increase in AWP.[11] GIF(D) ¶ 22; Pl.'s Ex. 46. Finally, when Mylan raised its prices on Lorazepam and Clorazepate, the AWP for those products rose as well. GIF(D) ¶ 22; see Saha Reb.[12] at 18-20.

Mylan also asserts that it has no knowledge or control over MAC prices. Memo(D) at 7; SMF(D) ¶ 11. Again, while it is undisputed that Mylan itself does not set the MAC pricing, whether the MAC price increased as a consequence of Mylan's price increase is disputed. There is evidence that Mylan monitored MAC prices, was aware that its own price increases would affect MAC lists and prices, and made efforts to have Lorazepam and Clorazepate removed from those lists. GIF(D) ¶ 11. Plaintiffs have proffered documents from Plaintiffs' PBMs that reveal

[11] Roderick Jackson, Senior Vice President of Mylan Pharmaceuticals, in a letter dated March 6, 1998 sent to pharmacy professionals, stated that after its generic price increases, Mylan was "pleased to note that pharmacy reimbursement using the new pricing is showing a significant improvement in gross profit dollars." Pl.'s Ex. 46. The letter went on to explain that the independent publishers of AWP, "First Data Bank, MediSpan, Red Book and other sources, were notified of the price adjustments in a timely manner to ensure adequate reimbursements." Id. Another Mylan document stated, "Mylan immediately notifies First Data Bank, Medi-Span, Red Book, HCFA, and all state Medicaid programs of AWP and/or WAC price modifications." GIF(D) ¶ 22; Pl.'s Ex. 46.

[12] Citations to "Saha Reb." refer to the Rebuttal Report of Dr. Atanu Saha, located at Plaintiffs' Exhibit 87.

significant increases in MAC prices, as well as deletion from the MAC list at some points, for Lorazepam and Clorazepate following the implementation of the exclusive agreements. See Plaintiffs Blue Cross Blue Shield of Minnesota, Blue Cross Blue Shield of Massachusetts and Federated Mutual Insurance Company's Motion for Leave to Supplement the Record ("BCBS Supp.") at Ex. 1 and 2. Further, the reason cited by one PBM for the MAC price increases for Lorazepam and Clorazepate is a "significant generic manufacturer price increase" on the exact dates Mylan implemented its price increases on each of those drugs. Id. at Ex. 1. Plaintiffs' expert found that the increase in the MAC prices for Lorazepam and Clorazepate "would not have occurred but for the exclusive agreement." Saha Dep. at 223.

It is undisputed that the third variable in the reimbursement rate formula, U&C charge, is established by pharmacies. Memo(D) at 7; GIF(D) ¶ 21. However, as a practical matter, the U&C charges often exceed Mylan's sales price significantly and thus invariably will be higher than the AWP discount price and the MAC price, making it highly unusual that Plaintiffs would be subject to the U&C price. Id. As Plaintiffs have proffered evidence that AWP and MAC prices are related to Defendants' actions, given the reimbursement formula, a reasonable jury could infer that the prices ultimately borne by Plaintiffs were related to Defendants' actions as well. Corroborating this inference is Plaintiffs' evidence that when Mylan raised its prices after entering into the exclusive agreements, the amounts paid by Plaintiffs increased dramatically as well. GIF ¶ 8; Saha Reb. at 18-20. Finally, Plaintiffs' expert has performed a statistical analysis of the relationship between Mylan's prices and Plaintiffs' ingredient costs. This analysis yielded the result that ninety-seven percent of the variability of Plaintiffs' ingredient costs is explained by Mylan's net prices. Saha Reb. At 20.

The material issue is not whether Defendants had direct control over Plaintiffs' reimbursement rates, but whether Plaintiffs' increased costs were a consequence of Defendants' actions. While the answer to the former question is undisputedly no, the answer to the latter is in dispute. Plaintiffs have proffered sufficient evidence to create a genuine issue of material fact as to whether Defendants' conduct in entering into the exclusive agreements and Mylan's subsequent price increases on Lorazepam and Clorazepate proximately caused third-party reimbursement rates to increase, thus injuring Plaintiffs.

Defendants also argue that Plaintiffs have failed to establish proximate causation in this case because Plaintiffs are unable to distinguish their overcharge-based antitrust injury from injury caused by other factors, such as price increases imposed by third party PBMs and pharmacies and Plaintiffs' own independent business decisions. Memo(D) at 14-16. Defendants cite two cases that found summary judgment to be warranted on the basis of failure to establish proximate causation because the plaintiffs improperly attributed all of their losses to the defendants despite the presence of significant other independent factors. See Ameritnet, Inc. v. Xerox Corp., 972 F.2d 1483 (8th Cir. 1992); Tremco v. Holman, 1997 WL 423575, *3 (Minn. Ct. App. July 29, 1997). Those cases held that a plaintiff is not required to show that the defendant's conduct was the sole cause of the damages; however, a plaintiff must demonstrate that the defendant's actions materially contributed to the injury. Id.

As previously discussed, while Plaintiffs' reimbursement rates are set by contracts with independent PBMs and pharmacies, there is a genuine dispute as to whether Defendants' conduct impacts the formulas by which those rates are determined. Plaintiffs have indeed proffered evidence of a significant link between Defendants' actions and Plaintiffs' damages. Contrary to

Defendants' assertions, Plaintiffs have not attributed their entire increased reimbursements for Lorazepam and Clorazepate tablets to Defendants' conduct. Plaintiffs' expert has accounted for intervening factors. See e.g., Saha Reb. at 22 ("The damages calculation in the April Report does account for and make the appropriate adjustment for these factors. . . [Dr. Saha describes his methodology for doing so]" (emphasis original)). Plaintiffs have proffered sufficient evidence to raise a genuine issue of material fact as to whether Defendants' actions materially contributed to Plaintiffs' injuries. Therefore, summary judgment is inappropriate on the basis of proximate causation.

2. *Damages*

Finally, Defendants argue that summary judgment is warranted because Plaintiffs' theory of damages is too speculative to permit recovery. Memo(D) at 16. After injury and causation have been shown, although the factfinder is not entitled to base a judgment on speculation or guesswork, the jury may make a just and reasonable estimate of the damage based on relevant data. Bigelow v. RKO Radio Pictures, 327 U.S. 251, 264 (1946). Defendants claim that Plaintiffs' damages calculation is fatally flawed because it (1) fails to isolate the damages attributable solely to Defendants' alleged misconduct, and (2) contemplates that the damages could continue indefinitely.

Plaintiffs are generally afforded wide latitude in selecting a damage theory. See, e.g., Danny Kresky Enters. Corp. v. Magid, 716 F.2d 206, 213 (3rd Cir. 1983). The courts have been liberal in designing rules of proof with respect to the amount of damages when the fact of damage is clearly established. Locklin v. Day-Glo Color Corp., 429 F.2d 873, 880 (7th Cir. 1970). In cases involving monopolistic overcharges, the measure of damages for a purchaser normally is the

difference between the price the purchaser paid and the price it would have paid absent the violation. See Hanover Shoe, Inc. v. United Shoe Mach. Corp., 392 U.S. 481, 487-88 (1968); Berkey Photo, Inc. v. Eastman Kodak Co., 603 F.2d 263, 297 (2nd Cir. 1979), cert. denied, 444 U.S. 1093 (1980). Indeed, Plaintiffs' calculation measures the damages they would not have incurred but for Defendants' illegal activities. In order to calculate these damages, Dr. Saha used a "before and after" method, as well as a "yardstick method." Opp.(D) at 13. These methodologies have been accepted as appropriate measures of damages in antitrust cases. Story Parchment Co. v. Patterson Parchment Paper Co., 282 U.S. 555, 561 (1931) (holding that the difference, if any, between the amounts actually realized by petitioner and what would have been realized by it from sales at reasonable prices except for the unlawful acts of the respondents was a permissible method of calculating damages); Bigelow, 327 U.S. at 266 (holding that before and after approach to damages is acceptable); Blue Cross & Blue Shield United of Wisconsin v. Marshfield Clinic, 152 F.3d 588, 592 (7th Cir. 1998) (holding that the yardstick method is an acceptable manner of calculating antitrust damages).

Plaintiffs are entitled to recover for injury caused by Defendants' conduct, including those damages that were incurred after the termination of the exclusive agreements, i.e., after any anticompetitive conduct ceased. See *In re* Cardizem CD Antitrust Litig., No. 99-md-1278, Order 80 at 63-64 (E.D. Mich., filed Nov. 13, 2003) (finding a genuine issue of material fact where Plaintiff offered evidence demonstrating that Defendant's anti-competitive conduct in pharmaceutical market produced damages beyond the date of generic entry); Day-Glo Color Corp., 429 F.2d at 883 (upholding award of damages after defendant's illegal antitrust conduct ended because the "effects of [the defendant's] prior unlawful acts were still making themselves

known"). Even after the termination of the exclusive agreements, Plaintiffs continued to pay "significantly higher" prices than they paid prior to the exclusive agreements. Saha Rep. at 9.

Defendants contend that Plaintiffs' damages analysis does not provide a reasonable estimate of damages because it does not attempt to determine that portion of Plaintiffs' increased payments attributable to Defendants' alleged misconduct. Memo(D) at 17. Any forces not caused by Defendants' illegal activities that were likely to have made the costs borne by Plaintiffs higher must be taken into account in order to make a responsible estimate of damages in this case. See Blue Cross and Blue Shield United of Wisconsin, et al. v. Marshfield Clinic, 152 F.3d 588, 593 (7th Cir. 1998). "Statistical studies that fail to correct for salient factors, not attributable to the defendant's misconduct, that may have caused the harm of which the plaintiff is complaining do not provide a rational basis for a judgment." Id. Defendants argue that Plaintiffs' economist fails to account for increases in Plaintiffs' payments imposed by other entities in the distribution chain.

Plaintiffs' expert, Dr. Saha, has provided a thorough model for assessing damages, and does take into account extraneous factors that may have contributed to Plaintiffs' injury. See, e.g., Saha Dep. at 237 (Pl.'s Ex. 124) ("the particular damages approach I take accounts for the actual changes in dispensing fee and co-payments, coinsurance, PBM contracts, PBM changes, all those factors that are occurring in the actual world and that impacts Mylan's cost, those are actually taken care of and accounted for accurately and correctly in a scientific fashion in the damage analysis I've undertaken"); Saha Reb. at 22 ("The methodology I employ isolates the harm caused by the Agreements from the other industry and market events.").[13]

[13] See also, Saha Rep. at 30 (describing methodology for controlling for change in PBM contract); id. (describing methodology for accounting for impact of co-payments, co-insurance, and deductibles on ingredient cost); id. at 31 (describing methodology for controlling for impact of dispensing fees on ingredient cost); id. (describing methodology for controlling for impact of

Defendants rely heavily on the fact that Plaintiffs' reimbursement costs do not consistently track Mylan's prices in the period after the agreements were executed: it is undisputed that in the two year period after the termination of the exclusive agreements, the reimbursement rates for Lorazepam rose 4% while Mylan's prices dropped 95%, and the reimbursement rates for Clorazepate dropped less than 1% while Mylan's price dropped 75%. SMF(D) ¶¶ 17, 18; GIF(D) ¶¶ 17, 19. According to Defendants, these facts demonstrate that the wholesalers and pharmacies in the distribution chain between Mylan and Plaintiffs increased their profits through an overcharge of their own, and that Plaintiffs' expert failed to take these "independent actors" into account in his damages analysis. Reply(D) at 9. Defendants' focus on these facts is somewhat misdirected, as the relevant issue is whether the continued elevation of Plaintiffs' costs for Lorazepam and Clorazepate after 1998 is a direct result of Defendants' implementation of the exclusive agreements and subsequent price increase. The issue is not whether Mylan's post-1998 pricing caused Plaintiffs' post-1998 costs to remain elevated, but whether the exclusive agreements did.[14] Plaintiffs' expert, Dr. Saha, found that Defendants' implementation of the exclusive agreements combined with the price increases on Lorazepam and Clorazepate, resulted in prices for those drugs that still have not fallen to their pre-1998 levels. Saha Rep. at 8-9, 30; Saha Reb. at 26. Dr. Saha has explained that after Plaintiffs' ingredient costs were elevated as a result of Defendants' actions, they were slower to return to a competitive equilibrium even after the

rebates on ingredient cost).

[14] Further, as to the divergence between Mylan's prices and Plaintiffs' reimbursement costs after the rescission of the exclusive agreements, there is a genuine dispute as to the closeness of the correlation between those two figures. Plaintiffs' and Defendants' experts disagree as to the degree of divergence between the drop in Mylan's prices after the agreements were terminated and Plaintiffs' reimbursements, as well as to the relationship between them. See Saha Dep. At 180 (Pl.'s Ex. 124); Saha Reb. At 16-18. This is a dispute between the two parties' experts that must be resolved at trial.

termination of the agreements because prices in the pharmaceutical industry may change infrequently, and price decline in certain conditions can be more gradual than price increase. Saha Reb. at 24. Within the pharmaceutical industry, it may take a few years before generic prices stabilize at a competitive equilibrium from an initial high level. Id.; Saha Rep. at 7, Ex. 2. There is a genuine dispute of fact as to whether the continued elevation of Plaintiffs' costs for Lorazepam and Clorazepate after 1998 is a direct result of Defendants' implementation of the exclusive agreements and subsequent price increase.

Defendants also argue that Plaintiffs' damages theory is unduly speculative because it continues indefinitely. Reply(D) at 9. According to Defendants, any measure of damages must be limited to the period in which the exclusive agreements were in effect. Plaintiffs' theory of damages does not continue indefinitely, but rather has a defined point of termination: "when the actual ingredient cost comes down to the level that is a competitive level, which is the '96-97 level adjusted for appropriate inflationary change in this industry, then the damages period would end." Saha Dep. at 216 (Pl.'s Ex. 32). Again, Plaintiffs' theory of damages is that but for the exclusive agreements, Plaintiffs' costs would not be at the high levels they are at today. The continuing inflation of their reimbursement rates is the consequence of Defendants' implementation of the exclusive agreements and subsequent price increases on Lorazepam and Clorazepate. Because there is a genuine dispute of material fact as to this relationship, summary judgment is inappropriate.

In order to survive summary judgment, Plaintiffs simply must present a "just and reasonable inference" for the computation of damages. See Eastman Kodak Co. of New York v. Southern Photo Materials Co., 273 U.S. 359, 379 (1927) (additionally holding that any uncertainty

regarding the appropriate quantum of damages is a question for the trier of fact). Plaintiffs' expert has submitted a complete and accurate measure of damages that is adequate to meet their burden here. A reasonable jury could estimate the plaintiffs' damages from Dr. Saha's reports. The exact amount of damages appropriate is an issue for the trier of fact, not summary judgment. Accordingly, Defendants' Joint Motion for Summary Judgment for Failure to Establish Causation and Damages is denied.

V. CONCLUSION

For the reasons stated above, the Court denies Plaintiff Blue Cross Blue Shield of Minnesota's Motion for Partial Summary Judgment, Defendants' Joint Motion for Summary Judgment for Failure to Establish Liability, and Defendants' Joint Motion for Summary Judgment for Failure to Establish Proximate Causation and Damages. An appropriate Order will accompany this Opinion.

March 29, 2005

Thomas F. Hogan
Chief Judge